“TISSUE GLUE AS AN ALTERNATIVE METHOD OF SKIN APPROXIMATION IN PATIENTS UNDERGOING CIRCUMCISION – A ONE YEAR RANDOMIZED CONTROLLED TRIAL AT KLES DR. PRABHAKAR KORE HOSPITAL AND MRC”

REG NO. BH0112001

Dissertation

Submitted to the
KLE University, Belgaum, Karnataka

In Partial Fulfillment
of the requirements for the degree of

MASTER OF SURGERY (M.S.)
in
GENERAL SURGERY

DEPARTMENT OF SURGERY,
JAWAHARLAL NEHRU MEDICAL COLLEGE,
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ENDORSEMENT

This is to certify that the dissertation entitled **"TISSUE GLUE AS AN ALTERNATIVE METHOD OF SKIN APPROXIMATION IN PATIENTS UNDERGOING CIRCUMCISION – A ONE YEAR RANDOMIZED CONTROLLED TRIAL AT KLES DR. PRABHAKAR KORE HOSPITAL AND MRC"** is a bonafide research work done by **CANDIDATE REG NO. BH0112001.**

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LIST OF ABBREVIATIONS USED

AAP	-	American Academy of Paediatrics
ACOG	-	American College of Obstetricians and Gynaecologists
AIDS	-	Aquired immunodeficiency syndrome
BMA	-	British Medical Association
BP	-	Blood pressure
BXO	-	Balanitis Xerotica Obliterans
cm	-	Centimeter
CNS	-	Central nervous system
CVS	-	Cardiovascular system
DNA	-	Deoxyribonucleic acid
DOA	-	Date of admission
DOD	-	Date of discharge
DOS	-	Date of surgery
e.g.	-	For example
ESR	-	Erythrocyte sedimentation rate
GMC	-	General Medical Council
HIV	-	Human immunodeficiency virus
HPV	-	Human papilloma virus
INR	-	International normalized ratio
Min	-	Minutes
mmHg	-	Millimeters of mercury
n	-	Total number
p	-	Probability
PT	-	Prothrombin time

RR	-	Respiratory rate
SD	-	Standard deviation
STDs	-	Sexually transmitted diseases
UK	-	United Kingdom
USA	-	United States of America
UTIs	-	Urinary Tract Infections
WHO	-	World Health Organization

ABSTRACT

Background and objectives

Traditionally, the circumcision wound was closed by absorbable sutures. Recently the use of tissue adhesive had evoked immense interest in the field of wound healing. This study was planned to compare tissue glue approximation with conventional suture method in terms of time consumed and incidence of infection in patients undergoing circumcision.

Methodology

This one year randomized controlled trial was performed on a total of 70 patients undergoing circumcision at Department of General Surgery, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum from January 2013 to December 2013. Patients were randomized by assigning even numbers to patients in group B (skin approximation by cyanoacrylate tissue glue) and odd number to those in group A (skin approximation by suture method). Operative time was noted and patients were examined for infection and other complication on the post operative day three and seven and.

Results

Majority of the patients were in the age group of three to six years (82.86% in group A and 80% in group B; p=1.000). The mean age was comparable in group A and B (5.51 ± 2.65 vs 5.32 ± 2.75 years; p=0.771). Further the clinical presentation, indications for circumcision, clinical examination findings and surgical characteristics were comparable in group A and B (p>0.050). Surgical time in group B was significantly less compared to

group A with a difference of nearly more than five minutes (19.14 ± 5.54 vs 24.97 ± 3.93 minutes; $p<0.001$). On day three wound assessment, significantly lower rate of complications was noted among the patients with group B regard to tenderness and oedema ($p<0.050$). During day seven assessment also significantly lower number of patients had oedema and discharge in group B compared to group A ($p<0.050$).

Conclusion and interpretation

Skin approximation by cyanoacrylate tissue glue results in significant reduction of surgical time with lower rates of complications compared to skin approximation by suture method.

Keywords

Circumcision; Cyanoacrylate tissue glue; Skin approximation; Suture;

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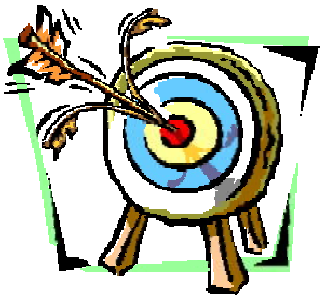

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INTRODUCTION

Circumcision is one of the most common surgical procedures carried out all over the world. It is performed for a number of therapeutic and non-therapeutic reasons. The normal penis consists of a cylindrical shaft and rounded tip (glans penis) separated by a groove, the coronal sulcus. The fold of skin (foreskin) covering the glans is removed during the circumcision procedure to a point near the coronal sulcus. Earliest description of circumcision was found in cave drawings and Ancient Egyptian tombs.[1,2]

According to the World Health Organization (WHO), global estimates suggest that 30% of males are circumcised.[3] Ritual circumcision is common in Jewish and Islamic faiths and in sub Saharan Africa. Also, it was estimated that 69 to 97% of all males in the USA are circumcised, in comparison with 70% in Australia, 48% in Canada and 24% in the United Kingdom. The reported prevalence of the procedure in the United States increased from about 30% in the 1930s to nearly 80% in the early 1970s.[4] Nelson et al[5] noticed a significant increase in the rate of newborn circumcision in USA, according to data taken from the nationwide inpatient sample. The increased incidence is attributed to perceived health benefits, particularly improved hygiene and reduced penile cancer.13 In India incidence of circumcision in general population is approximately 33%.[6] Most circumcisions are performed during adolescence for cultural or religious reasons. The prevalence of circumcision varies mostly with religious affiliation, and sometimes due to culture.[1]

Circumcision is usually performed for social, religious or medical reasons. The common medical indications for circumcision are usually seen in adults.

Medical reasons for circumcision include phimosis, paraphimosis, trauma, recurrent skin infections and lesions, like preputial cysts, redundant foreskin, and dyspareunia due to short frenulum. Phimosis which means narrowing of the preputial orifice is the most common medical indication for circumcision in all age groups. Severe phimosis may cause pain on voiding, urinary retention, urinary tract infections, localized skin infections, and calculi, and later in life may be associated with sexual dysfunction and squamous-cell carcinoma. Adhesions developing between the foreskin and the glans and preventing it to become retractile is another indication for circumcision. Secretions may collect under the foreskin producing infections and subsequent balanitis, or it may produce phimosis. Adult and adolescent circumcision in India is commonly carried out using dorsal slit method or sleeve method under local anesthesia. All the methods of adult and adolescent circumcision require suturing and dressing and absorbable sutures have traditionally been used for closure.[7]

Surgical complications of male circumcision can include excessive bleeding, hematoma formation, sepsis, unsatisfactory cosmetic effect, lacerations of the penis and injury to the glans, too little or too much of foreskin excised, meatal stenosis, urinary retention, phimosis and buried penis. Among all these complications, hemorrhage and infection are the most common complications.[1]

In the modern time with the advent of elective surgery, more energy has been directed for achieving an efficient and uncomplicated healing of the deliberately inflicted wound. Every surgeon dreams of perfect wound healing while performing surgeries. Although spectacular achievements are made in science and technology in recent years, yet the oldest problem of perfect wound closure still persists. The use

of tissue adhesive as an attractive alternative to sutures has recently evoked immense interest in the field of wound healing.[1]

The present study was an attempt to compare tissue glue approximation with conventional suture method in terms of time consumed and incidence of infection in patients undergoing circumcision.

OBJECTIVES

The objectives of the study were to compare tissue glue approximation with conventional suture method in terms of time consumed and prevalence of infection in patients undergoing circumcision.

REVIEW OF LITERATURE

The human anatomy has been the object of scientific study since the sixteenth century, but surprisingly little is known about the structure and function of the penile prepuce (foreskin). Frequently, it is surgically removed shortly after birth by the procedure called circumcision. Although, it is the world's oldest known planned surgical procedure, no consensus has been defined till now about its performance. Many authors proposed that the prepuce is not 'vestigial' but in fact a critical component of the male sexual anatomy. There are ectopic sebaceous glands on the inner preputial surface producing natural emollients and lubricants, necessary for normal sexual function. Other authors said that the cause of preputial moistening is the secretions of prostate, seminal vesicles and urethral glands.[7]

Historical background of circumcision

The origination of male circumcision is not known with certainty. However, it has been suggested that the procedure originated in Egypt over 15,000 years ago and spread throughout heliolithic cultures across the world during prehistoric migration.[8] Egyptian mummies and wall carvings offer some of the earliest recorded history of circumcision dating back to at least 6000 years ago.[9] In ancient Egypt, prior to biblical times, circumcision was performed to improve male hygiene.[7]

Figure 1. Circumcision in Ancient Egypt[7]

Later, routine circumcision of male infants was a part of the Abrahamic covenants with Jehovah, giving rise to religious circumcisions that continues until today in the Jewish and Muslim faiths. Then, circumcision of male infants has been advocated by Western culture as a preventive health measure.[7] Originating in the mid-19th century, 'routine' circumcision became widespread in white English-speaking nations, in the hope of reducing the incidence of venereal disease.[10] Also, in the early 1900s, circumcision was suggested as a way to prevent masturbation and tuberculosis.[7]

Nowadays, many groups opposing neonatal circumcision have been formed and have become visible lobbyists. Examples include the National Organization to Halt the Abuse and Routine Mutilation of Males, San Francisco, and the National Organization of Circumcision Information Resource Centers based in San Anselmo,

California, with branches across the United States and in Canada and other countries.[4]

Anatomy[11-14]

Gross Anatomy[11-13]

The penis is composed of two corpora cavernosa and one unpaired corpus spongiosum. The corpora contain oddly shaped cavities, which are lined with endothelium. Smooth muscle runs through the walls and septa of the corpora. The afferent arteries are notable for their strong smooth muscle wall.

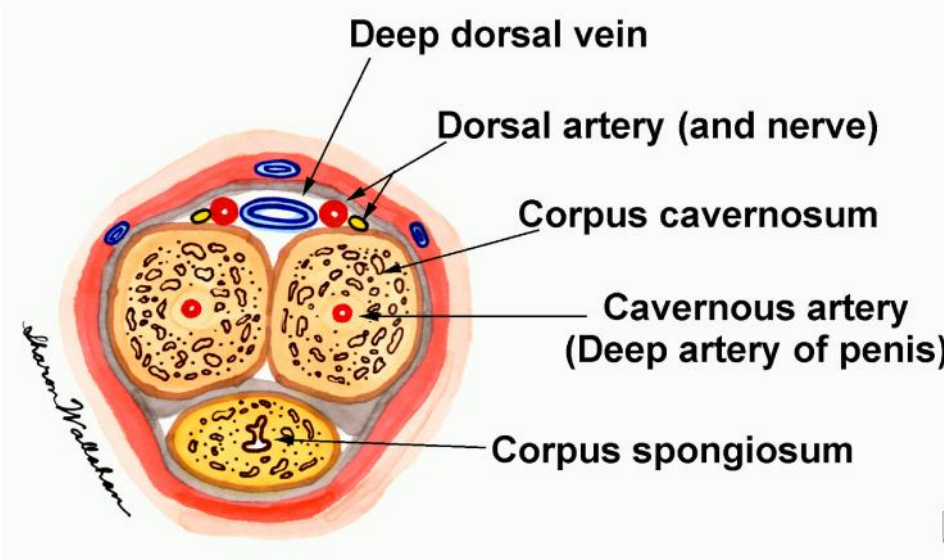


Figure 2. Cross-section through the body of the penis[13]

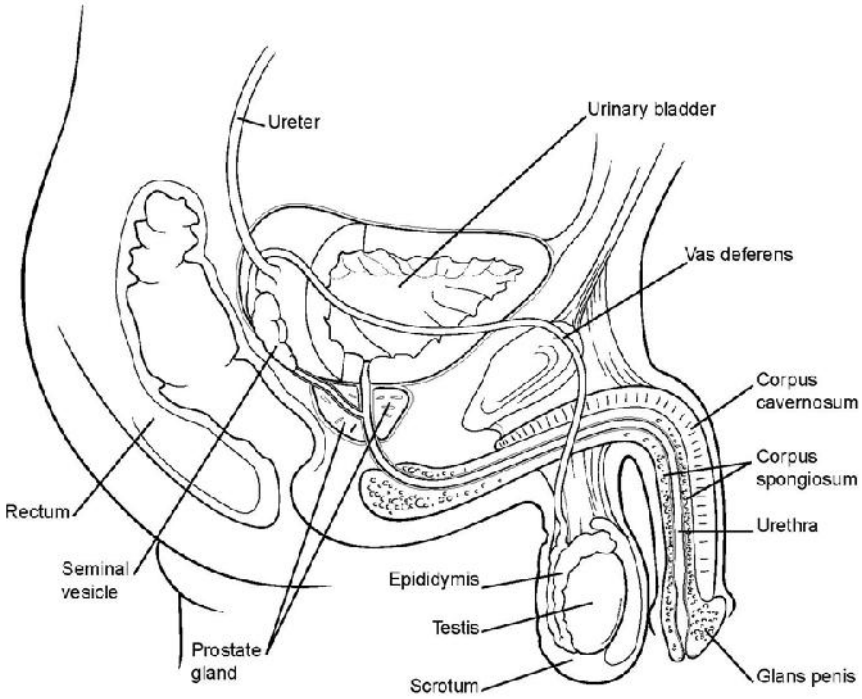


Figure 3. Male reproductive organs, sagittal section[13]

Corpora cavernosa penis: Each corpora cavernosa begins at the inferior ramus of the pubic bone (*crura penis*) and extends through the penis to the glans. Two muscles ischiocavernosi surround the corpora cavernosa.

Corpus spongiosum penis: The unpaired corpus spongiosum surrounds the urethra and begins between the two crura penis as a thickening (*Bulbus penis*). At the tip of the penis, the corpus spongiosum forms the glans penis. Connective tissue fibers provide a strong connection to the corpora cavernosa. The muscle bulbocavernosus surrounds the bulb of the penis.

Glans penis: Conical shaped end of the corpus spongiosum. The urethra ends with the *external urethral orifice* or *meatus urethrae externus* at the tip of the glans. The *Corona glandis* forms a sulcus and marks the transition from corpus spongiosum to the corpus cavernosum.

Tunica albuginea of the penis: A strong 1 mm thick fascial sheath surrounds the outside of the two corpora cavernosa and forms a septum in between (*Septum pectiniforme penis*).

Fascia and Ligaments of the Penis[11-13]

The Penis (tunica albuginea of the corpora cavernosa) is circularly surrounded by the Buck's fascia (*Fascia penis profunda*). The *fascia penis superficialis* lies above the Buck's fascia with smooth muscle from the *tunica dartos*. The *fascia penis superficialis* connects caudal to the superficial perineal fascia *(Colles' fascia)* and cranial to the *Scarpa's fascia*. The above-mentioned attachments of the fascia penis superficialis restrict penile haematomas to the area between the inguinal ligament.

The corpus spongiosum possesses a much thinner and more elastic tunica albuginea to allow for distention of the corpus spongiosum for passage of the ejaculate through the urethra. The thinner tunica albuginea of the corpus spongiosum also allows the corpus to become less rigid during erection. Hence, the distal extension of the spongiosum, the glans penis, covers the tips of the corpora cavernosa to provide a cushioning effect. The urethral meatus is positioned just slightly on the ventral surface of the glans and is slitlike. The edge of the glans overhangs the shaft of the penis, forming a rim called the corona.[14]

The three erectile bodies are surrounded by deep penile (Buck) fascia, the dartos fascia, and the penile skin. The deep penile (Buck) fascia is a strong, deep, fascial layer that is immediately superficial to the tunica albuginea. It is continuous

with the deep fascia of the muscles covering the crura and bulb of the penis, the ischiocavernosus and bulbospongiosus.[14]

On the dorsal aspect of the corpora cavernosa, the deep dorsal vein and paired dorsal arteries and branches of the dorsal nerves are contained within the deep penile (Buck) fascia. This fascia splits to surround the corpus spongiosum, and it extends into the perineum as the deep fascia of the ischiocavernosus and bulbospongiosus muscles. The deep penile (Buck) fascia encloses these muscles and each crus of the corpora cavernosa and the bulb of the corpus spongiosum, adhering these structures to the pubis, ischium, and the urogenital diaphragm.[14]

The penile ligaments attach the penis to the symphysis and the linea alba of the rectus sheath (*fundiform ligament* and *suspensory ligament*).

Male Urethra[11-13]

The male urethra can be divided in the following sections

Prostatic urethra: 3–5 cm long. The *colliculus seminalis* is located in the middle of the prostatic urethra. At the colliculus seminalis, also called verumontanum, end the *ejaculatory ducts* and pass into the urethra. The *prostatic utricle* is a relic of the embryonic period (Müllerian duct) in the midline of the prostatic urethra.

Membranous urethra: Part of the urethra, which runs through the pelvic floor and is enclosed by the external urethral sphincter *(M. sphincter urethrae externum)*.

Spongy urethra: Consists of the bulbar and penile urethra. The Cowper's glands flow into the proximal spongy urethra. The urethral glands (Littre's glands) open on the entire length of the urethra.

Vascular Supply of the Penis

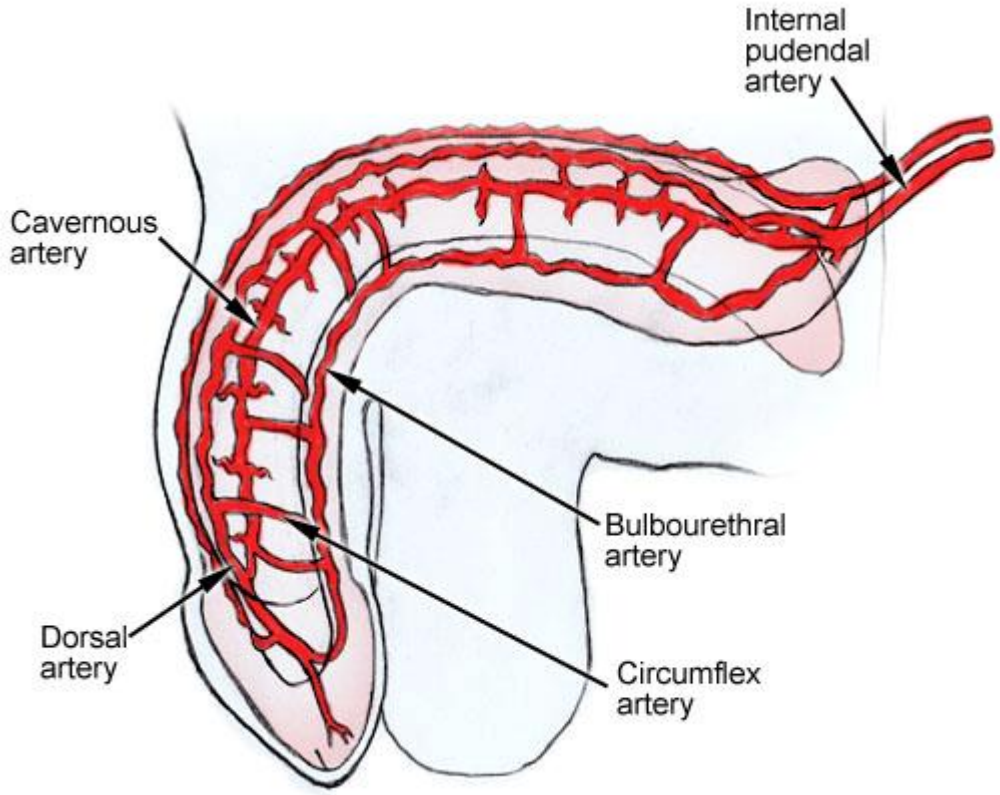


Figure 4. Arterial supply of the penis[14]

Arterial supply

Arteries of the penis: All of the penile arteries arise from the internal pudendal artery from the internal iliac artery. The internal pudendal artery reaches the ischiorectal fossa by the Alcock's canal.[11-13]

Blood supply to the skin of the penis is from the left and right superficial external pudendal arteries, which arise from the femoral artery. The superficial external pudendal arteries branch into dorsolateral and ventrolateral branches, which collateralize across the midline. In addition, branches in the skin form an extensive subdermal vascular plexus.[14]

The blood supply to deep structures of the penis is derived from a continuation of the internal pudendal artery, after it gives off the perineal branch. Three branches of the internal pudendal artery flow to the penis.[14]

1. The artery of the bulb (bulbourethral artery) passes through the deep penile (Buck) fascia to enter and supply the bulb of the penis and penile (spongy) urethra and corpus spongiosum.[14]

2. The dorsal artery travels along the dorsum of the penis between the dorsal nerve and deep dorsal vein and gives off circumflex branches that accompany the circumflex veins; the terminal branches are in the glans penis[14] and supply the glans, the prepuce and penile skin.[11-13]

3. The deep penile (cavernosal) artery is usually a single artery that arises on each side and enters the corpus cavernosum at the crus and runs the length of the penile shaft, giving off the helicine arteries which flow into caverns of corpus cavernosa and an integral component of the erectile process.[14]

Venous drainage

Veins of the penis: The veins of the penis break through the tunica albuginea and open via the circumflex veins in the unpaired *deep dorsal vein*, which empties into the venous plexus of Santorini. The *superficial dorsal vein* lies external to Buck's fascia.[11-13]

The penis is drained by three venous systems, the superficial, intermediate, and deep.[14]

Superficial veins are contained in the dartos fascia on the dorsolateral surface of the penis and coalesce at the base to form a single superficial dorsal vein, which usually drains into the great saphenous veins via the superficial external pudendal veins.[14]

The **intermediate system** contains the deep dorsal and the circumflex veins, lying within and beneath the deep penile (Buck) fascia. Emissary veins begin within the erectile tissue of the corpora cavernosa and course through the tunica albuginea and drain into the circumflex or deep dorsal veins. The circumflex veins arise from the spongiosum and often, the emissary veins drain into them.[14]

The circumflex veins course laterally around the cavernosa, passing beneath the dorsal arteries and nerves and drain into the deep dorsal vein. The deep dorsal vein lies in the midline groove between the 2 corpora cavernosa and is formed from 5-8 veins emerging from the glans penis, forming the retrocoronal plexus. It receives blood from the emissary and circumflex veins and passes underneath the symphysis pubis at the level of the suspensory ligament, leaving the shaft of the penis at the crus and draining into the prostatic plexus.[14]

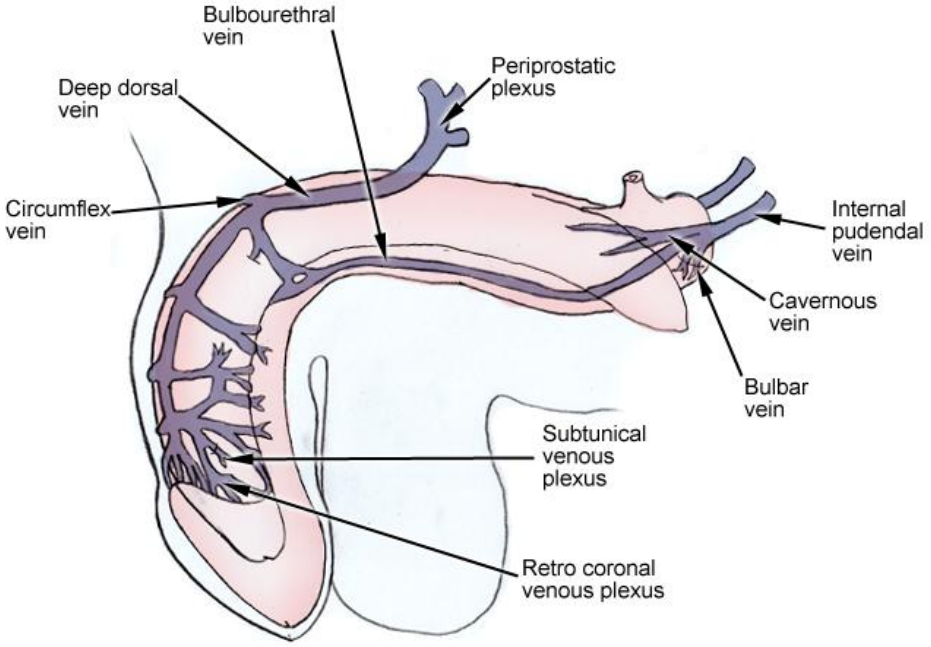


Figure 5. Venous drainage of the penis[14]

Deep venous drainage is via the crural and cavernosal veins. The crural veins arise in the midline, in the space between the crura. The cavernosal veins are consolidations of the emissary veins, which join to form a large venous channel that drains into the internal pudendal vein. Three or 4 small cavernosal veins course laterally between the corpus spongiosum and the crus of the penis for 2-3 cm before draining into the internal pudendal veins.[14]

Lymphatic drainage

Lymphatic drainage from the glans penis drains into large trunks in the area of the frenulum. These lymphatic vessels then circle to the dorsum of the corona and unite, coursing proximally beneath the deep penile (Buck) fascia, terminating mostly in the deep inguinal nodes of the femoral canal. Some lymphatic drainage is to the

presymphyseal lymph nodes and to the lateral lymph nodes of the external iliac lymphatics.[14]

Lymphatic vessels of the penis: Flow into the superficial inguinal and subinguinal lymph nodes. The proximal urethra drains into the pelvic lymph nodes (internal iliac and common iliac lymph nodes).[11-13]

Innervation of the Penis[11-13]

CNS: The processing of sensory stimuli in the limbic system and hypothalamus stimulates the spinal autonomic centers of the erection. The main centers in the hypothalamus are the paraventricular nucleus and the medial area praeoptica. The neurotransmitters of these first neurons are Oxytocin, melanocortin and dopamine.

Spinal autonomic centers: Cortical and peripheral stimuli activate spinal centers and cause the erection. The Nucleus intermediolateralis (S2–S4) is the parasympathetic spinal center, the sympathetic spinal center is located at T12–L2.

Inferior hypogastric plexus: Gets nerve fibers from the above mentioned centers. The inferior hypogastric plexus sends nerve fibers to the pelvic organs.

Cavernous nerves of the penis: Autonomic nerve fibers for the penis from the inferior hypogastric plexus are located posterolateral to the seminal vesicles and pass lateral to the prostate (mainly located between 5 to 7 o'clock). In the membranous portion of the urethra, the nerve fibers are located at 3 and 9 o'clock, at the distal bulb of penis they are located at 1 and 11 o'clock, where they enter into the penis. In addition, nerve fibers accompany the arteries or sensory nerves. The autonomic nerve fibers innervate the helicine arteries. The cholinergic nerve endings stimulate

the NO-synthase and therefore the release of NO (nitric oxide). The exact mechanism is explained in the section physiology of erection.

Motor neuron innervation: The pudendal nerve (S2-4) innervates the M. bulbo spongiosus and M. ischiocavernosus.

Sensory innervation: Afferent nerve fibers from the receptors via the dorsal penile nerve and pudendal nerve into the spinal cord. Next steps are either the medial lemniscus or spinothalamic tract.

Histology of the Penis[11-14]

Histology of the male urethra: The wall of the urethra consists of a *mucosa* with varying epitheliums (prostatic urethra with transitional epithelium, spongy urethra with stratified columnar epithelium, fossa navicularis with squamous epithelium), a *submucosa* with connective tissue and glands, and a very thin muscularis.

Histology of the Glans and prepuce: Keratinized squamous epithelium.

Histology of the erectile tissue: The corpora contain septa of smooth muscle, which form bizar shaped cavities. Vascular endothelium lines the septa and cavities. The afferent arteries for the erectile tissue possess a strong muscularis.

Tunica albuginea: The tunica is composed of elastic fibers that form an irregular, latticed network on which the collagen fibers rest. The tunica albuginea is composed of an inner circular layer and an outer longitudinal layer. Emissary veins travel between the inner and outer layers of the tunica and often exit the outer layer in an oblique manner. The outer layer of the tunica compresses the emissary veins when the penis becomes engorged with blood.

Corpora cavernosa: The corpora cavernosa are 2 spongy cylinders. Within the tunica albuginea are the interconnected sinusoids separated by smooth muscle trabeculae and surrounded by elastic fibers, collagen, and loose areolar tissue. The terminal cavernous nerves and helicine arteries are intimately associated with smooth muscle. The sinusoids are larger in the center and smaller in the periphery.

Corpus spongiosum: The structure of the corpus spongiosum is similar to that of the corpora cavernosa, except that the sinusoids are larger and a much thinner outer layer of the tunica albuginea is present. The glans has no tunical covering.

Erectile tissue vessels: The helicine arteries, branches of the deep penile artery, supply the trabecular tissue and sinusoids. They are contracted and tortuous in the flaccid state and dilated and straight in the erect state. The venous drainage from the erectile tissue originates in the venules starting at the peripheral sinusoids beneath the tunica albuginea. They travel in the trabeculae between the tunica and the peripheral sinusoids, forming the subtunical venular plexus before exiting as the emissary veins.

Foreskin (prepuce)

The *prepuce* (foreskin) consists of an inner and outer leaf and covers the glans of the flaccid penis. The two skin sheets are movable against each other. The *frenulum* is located at the ventral side of the glans and attaches the prepuce to the glans. The *smegma* is a whitish glans and prepuce and arises due to a bacterial colonization of the desquamated epithelium.

The penile skin is continuous with that of the lower abdominal wall. Distally, the penile skin is confluent with the smooth, hairless skin covering the glans. At the

corona, it is folded on itself to form the prepuce (foreskin), which overlies the glans. The subcutaneous connective tissue of the penis and scrotum has abundant smooth muscle and is called the dartos fascia, which continues into the perineum and fuses with the superficial perineal (Colle) fascia. In the penis, the dartos fascia is loosely attached to the skin and deep penile (Buck) fascia and contains the superficial arteries, veins, and nerves of the penis.

Gross anatomy of the prepuce

The prepuce is a fold of skin that covers the glans. It is connected to the glans just below the urethral orifice by a fold called the frenulum.[15] The prepuce and glans penis enclose a potential cleft, the preputial sac, and two shallow fossae flank the frenulum.[16] The frenulum tethers the bottom of the prepuce to the ventral aspect of the glans. It restricts proximal movement of the ridged band and assists in returning the prepuce to its distal position over the glans.[17] In fact, the frenulum is collectively known as the "sex nerve" in France. It is hypothesized that its stretching during coitus forms a stimulus for ejaculation.[7]

Histological features of the prepuce

The prepuce looks like a double fold of skin.[15,16,18,19] Its outer layer represents an extension from the thin and dark skin of body of penis, at the corona of the penis. The inner layer is confluent at the neck of penis with the thin skin covering and adhering firmly to the glans.[15] There is no significant difference between the inner and outer foreskin keratin thickness in adults "25.37 ± 12.51 and 20.54 ± 12.51 μm respectively, p=0.451".[19]

Other authors reported that the prepuce is not a simple fold of skin, but it is a fold, bounded by skin externally and mucosa internally.[20-22] Its mucocutaneous junction resembles that of eyelids, lips, anus, and labia minora.[20] When retracted in uncircumcised penis, the inner surface of the prepuce displays two zones; ridged and smooth. The crests of the ridged zone contain numerous tactile nerve endings of Meissner (Meissner's corpuscles). They are not present in the sulci (furrows) between the ridges.[21]

The lamina propria of the prepuce is very vascular, which explains the common hemorrhagic complications associated with circumcision.[20] It is devoid of lanugo hair follicles, sweat and sebaceous glands.[22] Also, there is a mosaic of smooth muscle bundles and elastic fibers enclosed between the external and internal skin of the prepuce.[18] The muscle fibers represent extensions of dartos muscle which is specific to the male external genitalia. When comparing the dartos muscle layer of prepuce in males before and after puberty, the ratio of muscle fibers to elastic fibers decreases. This may explain why on gross inspection the distal prepuce is puckered in the infant and appears more relaxed in adults.[20]

Development of the prepuce

The prepuce develops early in intrauterine life as a fold originating at the coronal sulcus (the groove that demarcates the shaft from the glans penis). This fold inverts (the outside becoming the inside) as it grows forward over the glans. Shared epidermal cells of the glans and the advancing prepuce create a common balanopreputial membrane which firmly attaches the prepuce to the glans. The complete en-folding of the glans by the prepuce is accomplished by the twenty

fourth week.[17] Although the actual separation of the prepuce from the glans begins at 24 weeks of gestation, the inner preputial surface and the surface of the glans are contiguous and appear to be adherent at birth. Such adhesions are physiologic and universal during neonatal period and infancy.[23] Over the next years, preputial separation gradually occurs as the cells in the fused layers mature and desquamate. This separation occurs spontaneously along an age-related continuum, with approximately 90% of foreskins are retractable by three years of age.[24]

At birth and for the first few years of a male's life, the inside fold of the foreskin is attached or fused to the glans, in very much the way the eyelids of a newborn kitten are sealed closed. The tissue that connects these two surfaces dissolves naturally over time - a process that should never be hurried. Premature or forcible retraction can tear the foreskin from the glans causing pain, bleeding, infection, and even skin adhesions.[25]

The first person to retract a child's foreskin should be the child himself and no one else. The foreskin can be retracted when its inside fold separates from the glans and its opening widens. This usually happens by age 18. Even if the glans and foreskin separate by themselves in infancy, the foreskin may not yet be retractable because the opening of a baby's foreskin may be only large enough to allow for the passage of urine. As the genitals develop, the opening of the foreskin increases in size to allow the foreskin to retract. [25]

The age at which the foreskin becomes retractable is highly variable from one individual to another. Some boys have retractable foreskins by the age of 2, while others are not retractable until the age of 18. One flawed study said that the

foreskin should be retractable in all boys by the age of 5; this is not true. Each boy develops differently and there is no set age at which the foreskin must be retractable.[25]

Function of the prepuce

The function of the foreskin is uncertain, but protection of the underlying penile glans and meatus, as well as reduction of friction during sexual intercourse, has been proposed.60 It has been suggested that the moist lubricated male preputial sac provides for atraumatic vaginal intercourse.[20]

Functions[25]

Protection: The foreskin covers and protects the glans and urinary opening from abrasion, irritation, and foreign material.

Pleasure: The foreskin is the most sexually sensitive and pleasurable part of the penis. Because most adult men in America were circumcised at birth, there is a common misconception that the glans is the most pleasurable part of the penis. A specialized ridged band of tissue encircling the tip of the inner foreskin contains thousands of erogenous nerve endings which provide intact men with the majority of their sexual sensation, making the foreskin vital to the male sexual response. Circumcision removes this highly erogenous tissue, resulting in a dramatic reduction in sexual sensation.

Sexual: During intercourse, the intact penis glides back and forth inside its skin sheath, greatly reducing the friction between the penis and vaginal walls. Because of this, women report improved sensation and comfort with an intact penis.

Structural: The foreskin provides sufficient skin length to accommodate penis growth and allows for comfortable erections.

The foreskin, or prepuce, is a retractable, double-sided fold of skin and mucosal tissue that covers the glans, or head, of the penis. The foreskin is an integral and significant part of the overall penile skin system. The outside of the foreskin is like the skin on the shaft of the penis but the inner foreskin is mucosal membrane like the inside of the eyelid or the mouth. The foreskin contains blood vessels, nerve endings, and a thin layer of muscle.

The penile skin (including the foreskin) is free to move over the penile shaft because the double-sided nature of the foreskin makes the penile skin system considerably longer than the penile shaft and also because the penile skin is only connected to the underlying structures at the pelvis and at the base of the glans (at the sulcus). This ability to move is the hallmark physical characteristic of the penile skin system and it plays a vital role in intercourse.

Foreskin's Role as Sensory and Erogenous Tissue[25]

The foreskin's ability to detect touch, motion, vibration, temperature variations, texture, and moisture is unmatched in male sexual anatomy.

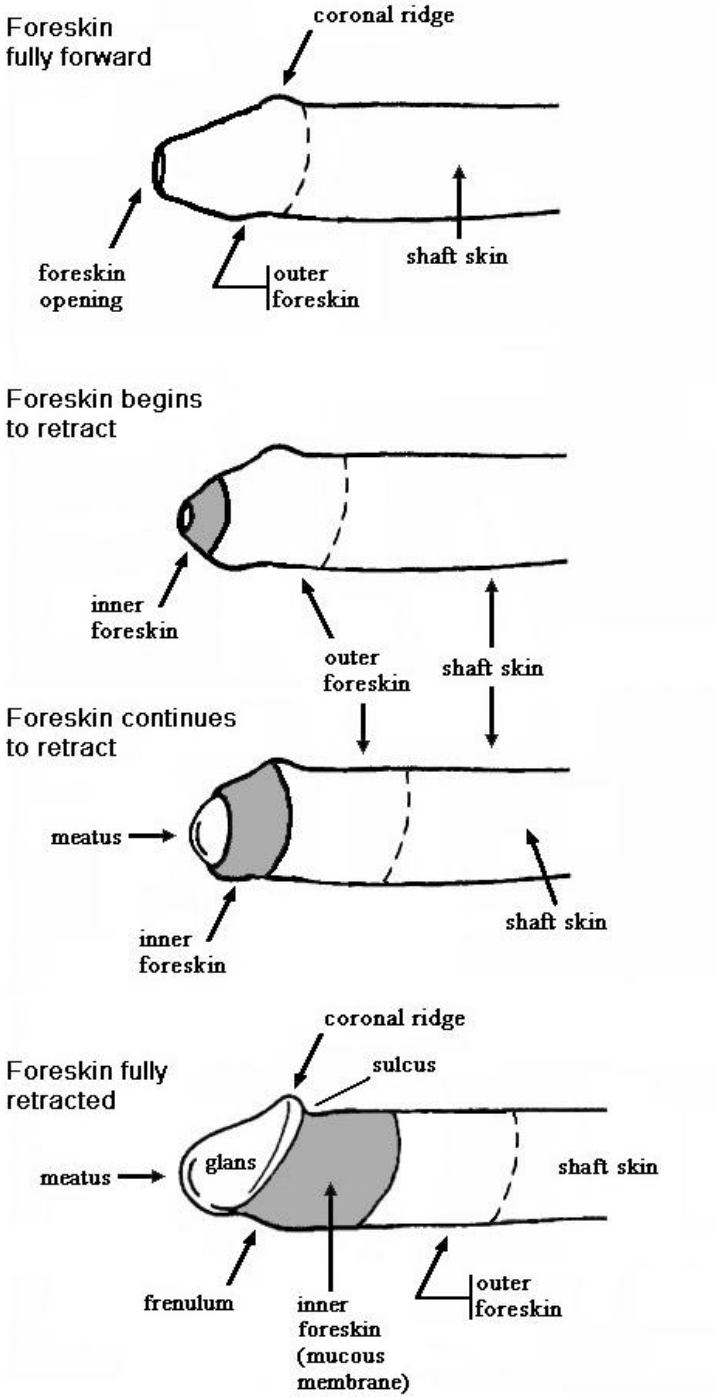


Figure 6. The foreskin retraction process[25]

The foreskin gives a man a tremendous amount of pleasure as well as detailed information about his sexual response. While the foreskin has fine-touch receptors, the glans, in contrast, has pressure receptors and lacks the fine-touch

receptors found in the foreskin. This is why the sensations provided by the foreskin are so different from the sensations provided by the glans. It is the combination of these two sensations that provide intact (uncircumcised) men with the full range of sexual feeling.

Infections[25]

Contrary to the uniquely American belief that the foreskin is prone to infection, most intact males live their entire lives without ever having a problem with their foreskin. When the occasional infection does occur, it can usually be treated with antibiotics.

The vast majority of infections of the foreskin are caused by premature or forcible retraction of a child's foreskin that has not yet separated from the glans. Premature or forcible retraction can tear the bond between the foreskin and glans causing bleeding and creating an opening for bacterial infection. All too often a doctor, baby sitter, or parent mistakenly believes that the foreskin must be retracted or cleaned in a young boy and the subsequent tearing and bleeding allows for an infection, which then leads to a conclusion that circumcision is required (or should have been done at birth). If the foreskin had just been left alone, there wouldn't have been a problem in the first place.

Ballooning during urination[25]

As a boy's foreskin begins to separate from the glans (and if the foreskin's opening is still small) his foreskin may expand (balloon) during urination. This is caused by the pressure of the urine, and is no cause for alarm. Ballooning will not

cause an infection. As the genitals develop and the foreskin's opening increases in size, the ballooning will subside.

Phimosis[25]

Phimosis is a condition where the foreskin cannot retract or cannot be retracted. A valid diagnosis of phimosis is possible only in *adult* males. Because the foreskin is fused to the glans at birth and slowly separates over time, a non-retractable foreskin is a *normal condition* in children. Two conditions must exist for the foreskin to become retractable: 1) the glans and foreskin must have separated and 2) the foreskin opening must have increased in size so it can stretch over the glans. Both of these happen over time as a boy matures, and each boy develops at a different rate. Some boys' foreskins are retractable at the age of 2; others aren't until the age of 18 - these variations are normal. A child's foreskin should never be forcibly retracted. The first person to retract a child's foreskin should be the child himself and no one else.

The vast majority of phimosis cases can be effectively treated without resorting to amputation of the foreskin (circumcision). The goal should be to help the foreskin become retractable, not to amputate it. Conservative treatment options include manual stretching, topical medications, and conservative surgical procedures to loosen the opening of the foreskin.

Paraphimosis[25]

Paraphimosis is a condition where the foreskin has been retracted and becomes trapped behind the head of the penis. This interferes with blood circulation in the penis and the result is edema, which is what causes the swelling. There is

normally no reason to believe that infection is present. It is sometimes described as looking like an inner tube is circling the penis right behind the glans or head of the penis. Paraphimosis is a medical emergency because circulation is impaired. The emergency is over when the foreskin is brought forward to its normal position.

The proper first aid is to squeeze the head of the penis between thumb and fore finger to force the blood out of the head so as to reduce its size at which time the foreskin may be brought forward. Circumcision is not needed, but doctors unfamiliar with proper treatment for paraphimosis may erroneously suggest it.

Urinary Tract Infections (UTIs) [25]

Urinary tract infections (UTIs) are bacterial infections of the urinary tract (kidneys, ureters, bladder and urethra) and are usually associated with congenital abnormalities of the urinary tract. Most UTIs can be treated with antibiotics. Some have advocated circumcision as a way to treat recurrent UTIs, but there is no medical evidence to support the idea that the foreskin causes them.

Balanitis[25]

Balanitis is an inflammation of the glans (not necessarily an infection) and can occur in both circumcised and intact males. It is infection and inflammation of the glans penis. It is common in children with poorly retractile foreskins.

Balanitis Xerotica Obliterans (BXO) [25]

Balanitis Xerotica Obliterans is a rare but relatively serious disease. It is usually distinguished by a ring of hardened tissue with a whitish color at the tip of the foreskin. The hardening of the tissue prevents retraction of the foreskin. This is a

subtype caused by the presence of lichen sclerosis and atrophicus on the glans penis and prepuce. It produces white scarring of the affected areas that may spread to the distal urethra. Recurrent BXO may produce meatal stenosis.

Prevalence of circumcision

It was estimated that 69 to 97% of all boys and men in the USA had been circumcised, in comparison with 70% in Australia, 48% in Canada and 24% in the United Kingdom. The reported prevalence of the procedure in the United States increased from about 30% in the 1930s to nearly 80% in the early 1970s. This is attributed to more births in hospital where routine circumcision was common due to perceived health benefits, particularly improved hygiene and reduced penile cancer.[4] Estimates based on the National Centre for Health Statistics indicate that 61 to 65% of male infants were circumcised in the USA during 1987 and 1995. There are also differences in circumcision levels across racial and ethnic groups in the USA and whites are more likely to be circumcised than are blacks or Hispanics (81% vs. 65% or 54%).[26]

There was, however, enormous variation between the circumcision rate in the UK (5–6%) and that in the USA (60%). In Britain neonatal circumcision declined from an incidence of around 30 percent in the 1940s to a very low level at present. Still, it remains a common operation, with over 30,000 procedures annually.[27]

In India incidence of circumcision in general population is approximately 33%.[6] Most circumcisions are performed during adolescence for cultural or religious

reasons. The prevalence of circumcision varies mostly with religious affiliation, and sometimes due to culture.[1]

Indications

Circumcision is usually performed for social, religious or medical reasons. The common medical indications for circumcision are usually seen in adults. Medical reasons for circumcision include phimosis, paraphimosis, trauma, recurrent skin infections and lesions, preputial cysts, redundant foreskin, and dyspareunia due to short frenulum. Phimosis is the most common medical indication for circumcision in all age groups. Severe phimosis may cause pain on voiding, urinary retention, urinary tract infections, localized skin infections, and calculi, and later in life may be associated with sexual dysfunction and squamous-cell carcinoma. Adhesions developing between the foreskin and the glans and preventing it to become retractile is another indication for circumcision. Secretions may collect under the foreskin producing infections and subsequent balanitis, or it may produce phimosis.[7]

Medical indications for circumcision

The absolute medical reasons for circumcision include phimosis and balanitis. Adhesions developing between the foreskin and the glans may prevent the foreskin becoming retractile. Secretions may collect under the foreskin producing infection and subsequent balanitis, or it may produce narrowing of the urethral opening (meatus) called meatal stenosis. These can be alleviated either by division of the adhesions or by circumcision. Phimosis has also been managed by the use of a triple incision as an alternative to circumcision for patients whose parents are concerned about long-term cosmetic and functional complications.[28]

There have been suggestions that many boys are circumcised for phimosis,[29-31] balanitis[4] and xerotica Obliterans[4] unnecessarily. It is commonly managed by circumcision, which removes the cause of the inflammation. Alternative surgical management has been explored. In an procedure called 'prepucioplasty' the narrow ring of skin is divided across and sutured along. This widens the narrowing of the foreskin without removing the foreskin.[4]

For this operation to be successful, the boys need to self retract after the operation for 2–3 months. Certain conditions require preservation of the foreskin and therefore circumcision is contraindicated. These are normally those conditions where the foreskin is required for surgical reconstruction of the penis following congenital disorders. Such conditions include hypospadias, epispadias, chordee, buried penis or a micropenis.[4]

Non-surgical management of phimosis and balanitis

It has been suggested that gentle stretching exercises to loosen and work the foreskin can reduce the tightness in phimosis and balanitis. Such management can take several months. The use of steroid creams as an adjutant to this has been explored. An 87% effectiveness rate in preventing circumcision has been reported.[32-34]

The religious precedents of circumcision

Religion is a commonly cited reason for parents seeking circumcision for their sons. Circumcision has been practised for centuries within Judaism and Islam. Circumcision is one of the oldest traditions within Judaism. The initial practice of this is laid down in the book of Genesis as the sign of a covenant between God and

the descendants of Abraham. The practice has been continued until today. In some Jewish communities there has been debate as to the need to continue circumcision or whether other practices define being Jewish while in others the practice is deemed essential.[4]

The practice is also followed within Islam. Although circumcision itself is not specified within the Koran, it is widespread and nearly all Muslim men will be circumcised before reaching puberty. The basis is enshrined within tradition, and the justification for this has been examined by a number of Muslim scholars. Muslims who are not circumcised may be subject to social exclusion. It is necessary to be circumcised before a Muslim may make the Hajj, the pilgrimage to Mecca.[4]

Circumcision has been described as a sign of social inclusion. The absence of circumcision for a male within a community in which the practice is common can cause social stigma. In cases of haemophilia, the high risk of bleeding makes non-therapeutic circumcision such as on religious grounds unsuitable.[4]

A study[35] in 2000 examined the psychological and social implications of this in Jews and Muslims. Most parents saw circumcision as a mandatory procedure. Significant numbers of haemophilic boys (60%) and their parents (82%) were found to have an inferiority complex because the boys are unable to be circumcised.

Current speciality and society recommendations for circumcision

American, Australian and Canadian American paediatricians are against routine circumcision of newborn infants and are of the opinion that an informed decision should be made regarding this. Parents should be made aware of the

potential risks and be provided the opportunity to discuss this decision. Moreover, if the decision has been made, then adequate analgesia must be provided.[4]

In a joint publication with the American Academy of Paediatrics, the American College of Obstetricians and Gynaecologists (ACOG) concluded, ‘‘newborn circumcision is an elective procedure to be performed at the request of the parents on baby boys who are physiologically and clinically stable’’. The current clinical policy on neonatal circumcision contained in the American Academy of Family Physicians Reference Manual states: current medical literature regarding neonatal circumcision is controversial and conflicting and the decision to perform neonatal circumcision should be based on the informed consent of the parents and requires objective, factual counselling of parents by the family physician.[36-38]

The British Medical Association (BMA) and the British General Medical Council (GMC) recommend that circumcision should be performed only for medical reasons.[39]

These guidelines also suggest, as with all aspects of medicine, doctors must act in the best interests of the patients and within the boundaries of the law. Failure to act appropriately disadvantages the patient and may lead to accusations of professional misconduct. The BMA guidelines allow for conscientious objection on the part of a doctor who does not wish to perform a non-therapeutic circumcision. These guidelines allow for religious circumcision and suggest that a religious representative is invited to be present to ensure religious requirements are met.[4]

Methods of circumcision[40]

Forceps-guided method of circumcision

This is a simple step-by-step procedure, which can be learnt by surgeons and surgical assistants who are relatively new to surgery. It can be used in clinics with limited resources, and it can be done without an assistant. A disadvantage of the procedure is that it leaves between 0.5 and 1.0 cm of mucosal skin proximal to the corona. The forceps-guided technique was used in the South African and Kenyan trials of circumcision and HIV infection. The version described here was standardized by the Kenyan study team.

Dorsal slit method of circumcision

The dorsal slit method requires more surgical skill than the forceps guided method. It is helpful to have an assistant present during the procedure, although it can be done without one. There is a risk that more skin is cut away from one side than the other, giving an asymmetric result. Nevertheless, the technique is widely used by general and urological surgeons throughout the world. It is the technique illustrated in the WHO manual, “Surgical care at the district hospital”.

Sleeve resection method of circumcision

The sleeve resection method requires good surgical skill and is better suited to a hospital rather than a clinic setting. The technique requires an assistant. If bipolar diathermy is available the procedure can be virtually bloodless. Although the cosmetic results are better than with the other two techniques, there is more room for

surgical error, either by cutting too deep when making the two circular incisions or cutting too deep when dissecting the skin flap free.

Analysis of the information on the benefits of circumcision

Medical benefits of circumcision

It has been suggested that circumcision produces a lower risk of urinary tract infection, confers protection against sexually transmitted infections, penile cancer and cervical cancer in the partner. It has also been suggested that circumcision may cause unnecessary pain to children who are circumcised and has a risk of complications due to surgery.[4]

Urinary tract infection (UTI) and circumcision

A number of recent studies have addressed the association between circumcision status and UTI. An association between an increased incidence of UTI and uncircumcised status has been reported. In 1982 a case series of 109 infants in whom UTI developed between 5 days and 8 months of age was reported. Male infants predominated in the series; of these, 95% were uncircumcised.[41]

A review of a cohort of 5261 infants born at an army hospital found a higher incidence rate of UTI among the uncircumcised male infants (4.12%) than among those who were circumcised (0.21%).[42] Anomalies of the urinary tracts of three out of eight patients who had a UTI after ritual circumcision has been reported.[43] Not circumcising male infants has been suggested, therefore, to be advantageous because it allows earlier identification of infants who have structural abnormalities that require surgical intervention or close medical follow-up.[44]

Despite the impressive magnitude of the decrease in the incidence of UTI (10-fold or more) associated with circumcision, when one recognises the low overall incidence rate of UTI among infant boys (1 to 2%), several questions arise. Can circumcision be advocated for the prevention of UTI? What are the risks and the costs of this approach? Are there any alternative strategies for the prevention of UTI that should be evaluated? Debate is continuing regarding this.[4]

Circumcision and prevalence of STDs including HIV

The association of circumcision and STDs including HIV and the hypothesis that circumcision might be protective against this virus has generated tremendous interest. The data on circumcision status and susceptibility to HIV infection and other sexually transmissible diseases have been recently reviewed.[4]

Five prospective studies involving heterosexual transmission of HIV-1 found a statistically significant association between uncircumcised and elevated risk for acquisition of HIV (relative risks 2.3–8.1).[45-49]

In the other two studies the relative risk exceeded three in uncircumcised men, but a low proportion of uncircumcised men and a small percentage of seroconversion limited the statistical power of these studies. Six studies by three different teams working in Rwanda, Uganda, Kenya and Tanzania[50-52] and the USA[53] found no relation between male circumcision and HIV status. The risk of contracting HIV was lower among circumcised men in the developing world, but this was not the case in developed countries.[54]

However a subsequent meta-analysis revealed inconclusive findings in many trials.[55] This analysis suggested it was protective in high-risk individuals particularly

in developing countries. Its benefit in the developed world is less well established. At least 16 studies have examined the relation between circumcision and sexually transmissible diseases other than HIV.

In a sample in South Africa 70% of noncircumcised men would prefer to be circumcised if it reduced the risk of STDs, Circumcised men believed they were at lower risk and so took part in more risky sexual behaviour.[56]

Regardless of these findings, behavioural factors are far more important risk factors for acquisition of HIV and other sexually transmissible diseases than circumcision status, and circumcision cannot be responsibly viewed as ‘‘protecting’’ against such infections.[4]

Circumcision and penile cancer

Male circumcision is associated with a reduced risk of penile human papilloma virus (HPV) infection and, in the case of men with a history of multiple sexual partners, a reduced risk of cervical cancer in their current female partners.[57] Like cervical cancer, the penile cancer is caused by high-risk (cancer causing) HPV.[58] The risks of developing cancer of the penis are almost eliminated by performing circumcision.[59] This effect appears to be a consequence of a lower incidence of infections with HPV and herpes simplex type 2.[60] For most cancers related to infectious organisms, chronic inflammation is an important component of pathogenesis. Moreover, some viruses incorporate their genetic materials directly into the host cell DNA.[61] Prostate cancer is another type of cancer to be noticed in uncircumcised men more than in the circumcised ones. Morris et al[62] concluded that a 1.6–2.0-fold higher risk of prostate cancer is contributed by the lack of

circumcision. It has been proposed that HPV may also play a role in the development of cancers of prostate.[63]

A number of case series published between 1932 and 1986 found that all penile cancers occurred inuncircumcised individuals.[64-71]

Results of one case control study provide an exception to this general rule, although circumcision status was determined by selfreport.[72] Nevertheless, this study also found that the absence of neonatal circumcision increased the risk for penile cancer by a factor of 3.2. Other identified risk factors for penile cancer are:

- Phimosis (occurring exclusively in uncircumcised males)
- Genital warts
- Infection with human papilloma virus
- Large number of sexual partners
- Cigarette smoking

The AAP policy notes that in the USA only nine to ten cases of penile cancer are diagnosed each year per 1 million men, indicating that although the risk is higher for uncircumcised men, the overall risk is extremely low. Because this disease is rare and occurs later in life, advocating circumcision as a preventive practice is not justified.[4]

Cervical carcinoma and circumcision

The viruses most commonly associated with cervical carcinoma are HPV 16 and HPV 18. Herpes simplex Type 2 is another causative agent. A higher-than-average risk of cervical cancer has been reported among the partners of men who

had been previously married to women with cervical cancer. As well, epidemiological studies have shown that starting sexual activity at an early age and having multiple sexual partners predispose women to cervical cancer. However, no relation has been established between exposure to uncircumcised sexual partners and cervical cancer.[4]

Analgesia in circumcision

Some traditional beliefs suggest that the earlier in life that circumcision takes place the less the pain felt by the child. Newborn infants exhibit physiological, autonomic and behavioural responses to noxious stimuli. These responses suggest that they experience pain, and there is evidence that preventing pain in newborns can be important.[73]

Behavioural differences have also been reported. Infants circumcised without an anaesthetic were reported to show decreases in responsiveness in comparison with those who received a dorsal penile nerve block.[74]

These differences were still evident a day after the procedure. Several methods to provide pain relief have been evaluated. Analgesic methods used include a mixture of local anaesthetics as a cream (2.5% lidocaine and 2.5% prilocaine), the dorsal penile nerve block and the subcutaneous ring block. The AAP notes that the subcutaneous ring block may provide the most effective analgesia.[4]

A recent study examined the effects of different analgesics on 132 children who were circumcised in the neonatal period. Those without analgesia showed the greatest pain response. Those with a dorsal or ring block showed the least. The

addition of oral sucrose solution reduced distress. This further advocates the use of analgesia in young children undergoing circumcision.[75]

Complications of circumcision[40]

Complications occurring during surgery

Excessive adhesions

If the patients has phimosis, so that the foreskin cannot be retracted prior to surgery, there is uncertainty about what will be found once the dorsal slit has been made and the foreskin retracted. If there are excessive adhesions, it may be difficult to separate the foreskin from the glans. Depending on the experience of the circumcision team, it may be better to stop the procedure and refer the man to a hospital. In this situation, the dorsal slit will have to be repaired, using stitches to stop bleeding.

It will not be possible to put on a dressing because the man will need to urinate. Nevertheless, the area should be kept as clean as possible. The wound should be covered with a gauze swab, which the man can keep in place by wearing tight underpants. Arrangements should be made for the man to attend the local referral hospital as soon as convenient, and in any case within 24–48 hours.

Excess bleeding during surgery

If there is excessive bleeding during the surgery, the first rule for the surgeon is not to panic. More damage is caused by panic attempts to stop bleeding than by the original injury. Place a swab under the penis and a second swab over the bleeding point, apply firm pressure, and wait five minutes (timed by the clock).

After five minutes, slowly lift off the swab. Often, the bleeding will have stopped Do not be tempted to look under the swab before five minutes have elapsed. If the bleeding has not stopped after five minutes, the site of the bleeding will be obvious. Apply a haemostatic artery forceps to the bleeding point. If this does not control the bleeding, apply pressure over a swab for a further 5 minutes (timed). At the end of this time, gently lift the swab again, and under-run the bleeding area with a suture. Remember that the larger blood vessels generally run along the length of the penis, and place the suture proximal to the bleeding (that is, on the side towards the base rather than the tip of the penis). It is very likely that these measures will control bleeding. If, exceptionally, the bleeding continues, the man should be transferred to a referral centre as an emergency, or a more experienced surgeon should be called to help.

Bleeding from the frenular artery

If there is excessive bleeding from the frenular artery, an under-running haemostatic stitch should be used to occlude the artery. Great care is needed not to bite too deeply, because the urethra is near to the surface skin and can easily be damaged.

Accidental injury

Accidental injury can include injury to the glans (e.g. partial severing of the glans) or too deep an incision, resulting in bleeding that is difficult to control. Any bleeding should be controlled by applying pressure over a piece of gauze, and the man should be transferred as an emergency to a referral centre. If the transfer time is likely to be long, insert a urinary catheter, wrap the penis in sterile gauze, and tape

the gauze in place. During the transfer, the patient should lie flat. At all times, the patient and his relatives should be kept informed about what has happened and what is going to be done. The risk of such accidents is reduced if the surgeon has received proper training and certification, and if there is a system of ongoing appraisal and recertification. Risks are higher if the surgeon becomes overconfident, or when time constraints result in operations being done in a hurry. To avoid this, countries need to have established and well-funded training and recertification procedures, and clinics need to ensure that adequate time is allowed for surgery.

Severing of the glans

If part or all of the glans has been severed, it should be wrapped in a sterile paraffin gauze to prevent drying and placed in a polyethylene bag. The man and his glans should be transferred as soon as possible to a referral centre, where it may be possible to reattach the glans.

Complications occurring within the first 48 hours after surgery

Bleeding is the most likely complication during the first 24–48 hours. A small amount of bleeding onto the gauze dressings is usual, but may alarm the patient. If he comes back to the clinic with blood-soaked dressings, these should be removed and the circumcision wound inspected for an obvious bleeding point. If there is fresh blood from the skin edge, a further suture should be inserted. This will require a full sterile procedure, as for the original circumcision, including local anaesthesia and sterile draping. Usually, placing one or two additional mattress sutures over the area will stop the bleeding.

Haematoma may form and may be associated with considerable bruising and skin discoloration. In general, haematomas are best left alone, unless they are very large or there is continued bleeding. The choice is between applying a further clean dressing and reviewing the situation in 24 hours, or applying a clean dressing and sending the patient to a referral centre. If the circumcision team is relatively inexperienced, it is safer to send the man to the referral centre.

Wound disruption is unusual in the first few days, but is sometimes seen in association with subcutaneous bleeding and haematoma formation, when the stitches cut out. In this situation the man should be sent to a referral centre. The specialist at the referral centre may decide either to suture the wound or to leave it to heal by secondary intention, depending on the state of the skin edges. If the disruption occurs within 48 hours of the operation, it is usually better for the clinic surgeon to explore and re-suture the wound.

Complications that occur within the first two weeks after surgery

Infection

After 2–3 days, the most likely problem is wound infection. An infection often causes increasing pain, and there may be visible signs, such as redness or purulent discharge. The patient should be given an appropriate antibiotic and advised to take frequent showers and to put a clean dressing on the wound between showers. If the infection is severe, the man should be advised to lie on his back, so that his penis is the highest point of his body. This promotes drainage of lymphatic fluid and speeds up the healing process. Sitting in a chair is a bad position.

Alternatively the wound can be left without a dressing, but should be protected from flies.

Wound disruption and cutting out of stitches

When stitches cut out, this usually indicates that there is an infection, and the patient should be given antibiotics. If more than 48 hours have passed since the operation, do not try to re-suture the wound, as the new stitches are likely to become infected and also cut out, making the situation worse. The wound should be left to heal by secondary intention. The man should be seen at the clinic as often as necessary until the wound has healed. In general, the healing process after infection leaves an untidy result, at least for the first few months. The man should be reassured that the appearance will usually become normal after about a year.

Worsening wound infection with signs of gangrene

A rare risk of genital surgery is infection with multiple bacteria, causing progressive skin loss. In this situation, the blood supply is cut off, and the skin becomes necrotic and turns completely black. This condition is known as Fournier's gangrene (synergistic gangrene or necrotizing fasciitis) and is more common in men who have diabetes. Any man with signs of spreading infection or black gangrenous skin should be urgently transferred to a referral centre. At the referral centre, it is usually necessary to give a general anaesthetic and remove all the dead skin.

Late complications

In the long term, the patient may complain of decreased sensitivity of the glans; oversensitivity of the glans; unsightly circumcision wounds, ragged scars or

other cosmetic concerns; persistent adhesions at the corona and inclusion cysts. These problems can be avoided if the foreskin is fully retracted during the operation and all adhesions carefully divided; discomfort during erection from the scrotal being skin pulled up the shaft of the penis and a tight scrotal sac. This can result from removal of too much skin during the circumcision. These problems can be avoided by careful preoperative marking of the incision lines.

Torsion (misalignment) of the skin of the penile shaft can be avoided by taking care during the operation to align the midline raphe with the frenulum. The incidence and nature of the various complications resulting from male circumcision has been the subject of much discussion, particularly among those groups who wish to have the practice ended for non-therapeutic reasons.[4] Adverse events may arise as an immediate acute result of surgery, or with effects that persist in the long term, e.g. the psychological and sexual effects.[4]

Further factors include the effect of a nonmedically qualified person performing the operation or the age at which the circumcision takes place. There have been reports of a lower incidence of certain complications such as adhesions with increasing age while other adverse events such as penile cancer appear more common with late circumcision. There are also differences in the incidence of such complications in different regions of the world.[76]

The overall rate of complication is a matter of debate and, in truth, unknown. Most circumcisions are performed without complication. The estimated rate of complication worldwide has been reported as lying between 0.1 and 35%.[77] The

power of these studies and the criteria for complication varies between these extremes.

In North America the rate of complication is estimated as lying between 0.2 to 2%.[78] There does appear to be evidence that the incidence of complications in the developed world is lower than that in the developing world. There are multiple confounding factors affecting this rate however.

Availability of healthcare, trained personnel and hygiene are all implicated, as is the method of data recording.

Physical adverse events

Physical effects following circumcision include pain, infection, haemorrhage, and incomplete circumcision.[79] Other complications cited include:[4]

- Recurrent phimosis
- Wound separation
- Concealment of the penis
- Meatal stenosis
- Inclusion cysts
- Unsatisfactory cosmetic appearance
- Urinary retention.

Anecdotal reports have been published of:[4]

- Necrotizing fasciitis
- Penile lymphoedema

- Amputation of the penis
- Urethro-cutaneous fistula.

Bleeding is a common adverse event seen in circumcisions. No clear incidence was found in the literature but it was estimated at around 1.6%.[79]

Most episodes are dealt with using pressure, cautery or sutures. Haemostatic agents may also be used. The tissue glue approximation of circumcision wounds in children has been found a feasible alternative, but offered no extra advantage to suturing.[80]

Infection affects a small percentage (0.002–0.63%) of circumcisions. However the incidence rate varies widely depending on technique, setting and the training of the surgeon. As with haemorrhage no clear rate was found in the literature with rates ranging from 0.63 to 0.002%.[77,79]

Infection can be treated with local or parenteral antibiotics, depending on the extent of infection. Due to differences in complication rate or severity no specific management technique can be recommended.

A study in 2000 found that some form of penile adhesions between any remaining foreskin and the glans develop following circumcision and the incidence decreases with increasing patient age. The reported incidence rate ranged from 2% in the eldest to 71% in the youngest under 12 months. Most of these resolved spontaneously with few requiring surgical resolution.[76]

Urethral stricture may also occur. A postoperative stricture rate of 11% requiring dilatation has been reported.[81]

Tissue glue to approximate the edges of the wound after circumcision

In the modern time with the advent of elective surgery, more energy has been directed for achieving an efficient and uncomplicated healing of the deliberately inflicted wound. Every surgeon dreams of perfect wound healing while performing surgeries. Although spectacular achievements are made in science and technology in recent years, yet the oldest surgical problem of perfect wound closure still persists. The use of tissue adhesive as an attractive alternative to sutures has recently been invoked immense interest in the field of wound healing.[1]

Circumcision is a commonly performed operation and absorbable sutures have traditionally been used for closure. The two most common complications of circumcision are bleeding and wound infection.[1] The cyanoacrylate tissue glue has been claimed to have the advantages of being hemostatic,[82] bacteriostatic[83,84] and easy to use.

Adult and adolescent circumcision is carried out using one of the methods: Dorsal slit method or sleeve method. Local anesthesia is the preferred method. The widely used dorsal slit method is used in the present study. All the methods of adult and adolescent circumcision require suturing and dressing. The circumcision wound was closed by absorbable sutures, traditionally. Currently, alternative methods are being utilized to overcome the shortcomings of the conventional closure like complications, postoperative pain, time consumed and cosmetic problems. The most recent advancement is the technique of closure without sutures. In the year 1940′s, variety of cyanoacrylate adhesives were developed which are series of homologous compounds known as alkyl-cyanoacrylates.[85]

These glues get polymerized on contact with basic substances such as blood or water. The polymerization occurs at room temperature and does not require the use of solvent or an added catalyst. The material can be spread easily in a thin film, readily wets the surfaces to which it is applied, and produces very little heat. It should not be placed inside the wound. Coover et al., has discovered the adhesive properties of cyanoacrylate adhesive and suggested their use as a surgical adhesive for the first time.[86]

Adhesive glue is especially useful for day care surgery like circumcision. Cyanoacrylate is a better alternative to sutures and gained increased clinical popularity due to the ease of application, decreased scarring, decreased pain and better cosmetic results with no discomfort as seen with sutures getting to or snagging the clothings and dressing.[87]

Randomised controlled trials in boys showed very low rates of wound disruption with tissue adhesive. A systematic review of circumcision in boys shows that tissue adhesive in circumcision reduces operative time, improves the cosmetic result and increases patient satisfaction when compared with sutures and was not associated with an increase in wound dehiscence. However, tissue adhesive closure in general surgery has a somewhat higher wound dehiscence rate compared with sutures.[88]

Tiwari et al.[89] showed a wound disruption rate of 6.8% (3/44) in boys and men (mean age 31 years) using tissue adhesive, while other case series including both men and boys found a very low rate of wound disruption.[90] However, these case series were small and follow-up rates were not clearly stated. Some authors

have cautioned against using tissue adhesive in adult circumcision because erections put tension on the wound, which could lead to dehiscence.

METHODOLOGY

The present one year randomized controlled trial was conducted in the Department of General Surgery, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum over a period, from 1st January 2013 to 31st December 2013.

Study design

The study design was randomized controlled trial.

Study period and duration

The present one year study was conducted from 1st January 2013 to 31st December 2013.

Place

This study was conducted under the Department of General Surgery, Urology and Paediatric Surgery, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum a teaching hospital attached to KLE University's Jawaharlal Nehru Medical College, Belgaum.

Source of Data

Patients posted for circumcision at Department of General Surgery, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum were studied.

Sample size

A total of 70 patients divided into two groups of 35 each were studied.

Sampling procedure

The sample size was estimated considering the 80% of the average three year hospital statistics as shown below.

Number of cases in 2010	-	78
Number of cases in 2011	-	97
Number of cases in 2012	-	87
Total	-	262
80% of average of three years	-	69.86

Hence the sample size of 35 in each group was planned for the present study.

Selection criteria

Inclusion

- Patients undergoing circumcision.
- Patients aged from one year to 70 years.

Exclusion

- Non compliant patients.
- Patients with malignancy.
- Patients with immunocompromised state.
- Patient with hypospadias

Ethical clearance

The study was approved from the Institutional Ethical Committee, Jawaharlal Nehru Medical College, Belgaum prior to the commencement.

Informed Consent

The patients fulfilling selection criteria were informed in detail about the nature of the study and a written informed consent was obtained. In case of children, parents / caregivers were explained about the study details and written informed consent was obtained (Annexure I).

Randomization

Randomization was done by assigning even numbers to patients in group B (study group) and odd number to those in group A (Control group). Patients were randomized into two groups of 35 each as below;

- Group A - Patients undergoing circumcision with skin approximation by suture method (n=35).
- Group B - Patients undergoing circumcision with skin approximation by cyanoacrylate tissue glue (n=35).

Method of collection of data

Data such as age and history was obtained through an interview. Further these patients were subjected to clinical examination and the findings were noted on a predesigned and pretested proforma (Annexure II).

Investigations

The following investigations were done.

- Routine blood counts – Hemoglobin, total leucocyte counts, differential counts, red blood cell counts and ESR.
- Blood grouping
- Blood urea nitrogen
- Serum creatinine
- Bleeding time
- Clotting time

Basic procedure

The operation was performed under spinal/caudal/general anaesthesia. The technique of dorsal slit followed by free hand cutting all around with sharp scissors was used in all the cases. The outer layer of the foreskin was retracted back and meticulous haemostasis was achieved.

Skin approximation

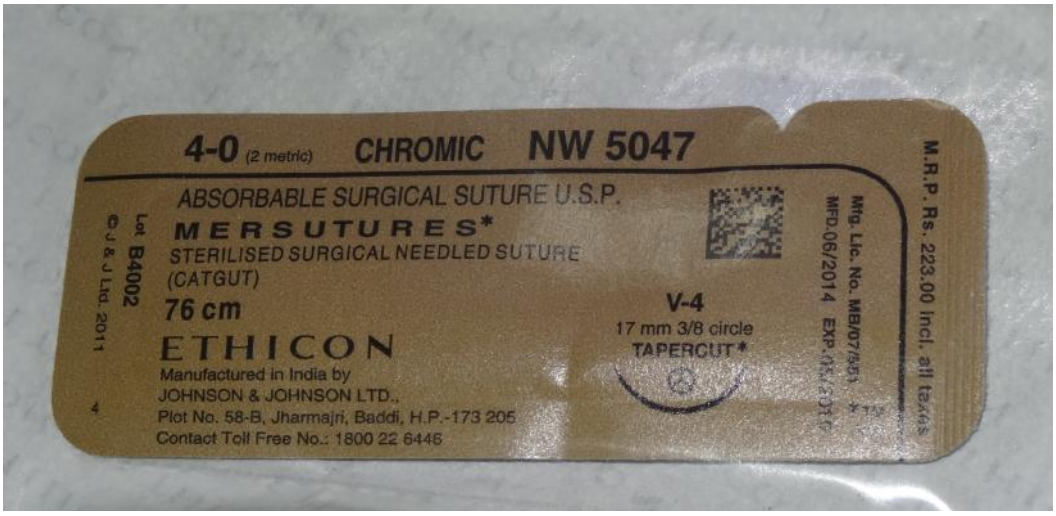
Group A

Patients underwent skin approximation by suture method using Plain Catgut 4-0 with round body needle, edge to edge, simple suture.

Group B

Patients underwent skin approximation by cyanoacrylate tissue glue.

Photograph 1. Cyanoacrylate tissue glue



Photograph 2. Chromic Catgut 4-0 suture

Photograph 3. Photograph after removal of foreskin

Photograph 4. Application of Cyanoacrylate glue

Photograph 5. Application of Cyanoacrylate glue

Photograph 6. Approximation of edge

Photograph 7. Immediate post operative glue application

Photograph 8. Wound appearance on post operative day seven

Photograph 9. Chromic Catgut 4-0 suturing

Photograph 10. Immediate Post operative after suturing

The glue 2-octyl cyanoacrylate was applied in two thin layers to the cut edges and then approximated with the help of forceps on either side in arc like fashion. The glue was allowed to dry and polymerize for 20 seconds. Leakage of the glue between the edges was avoided so that hardened glue does not catch the undergarments. The time of start of skin closure and the time of finishing the skin closure were noted down using a stopwatch timer. The time taken for skin closure was noted. No liquid or antibiotic ointment applied after glue application.

All the patients in the both groups received a 5 day course of amoxycillin and ibuprofen and paracetamol in appropriate doses. Bathing of the operative site was permitted after the 5^{th} day onwards.

Follow up

Patients were followed up at following intervals;

- Post operative day three.
- Post operative day seven.

Outcome variables

Patients were examined for infection and other complication on the post operative day three and seven.

Infection

Patients were evaluated for infection by assessing redness, tenderness, oedema and discharge. Other complications like allergy and skin necrosis were noted.

Statistical analysis

The data obtained was coded and entered in Microsoft Excel Spreadsheet. The categorical data was expressed as rates, ratios and percentages and comparison was done using chi-square test. Continuous data was expressed as mean ± standard deviation and the independent sample 't' test was used for comparison. A 'p' value of less than or equal to 0.05 at 95% confidence interval was considered as statistically significant.

RESULTS

This one year randomized controlled trial was conducted from 1st January 2013 to 31st December 2013 in the Department of General Surgery, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum. A total of 70 patients were studied. Randomization was done by assigning even numbers to patients in group B and odd number to those in group A.

- Group A - Patients undergoing circumcision and skin approximation by suture method.

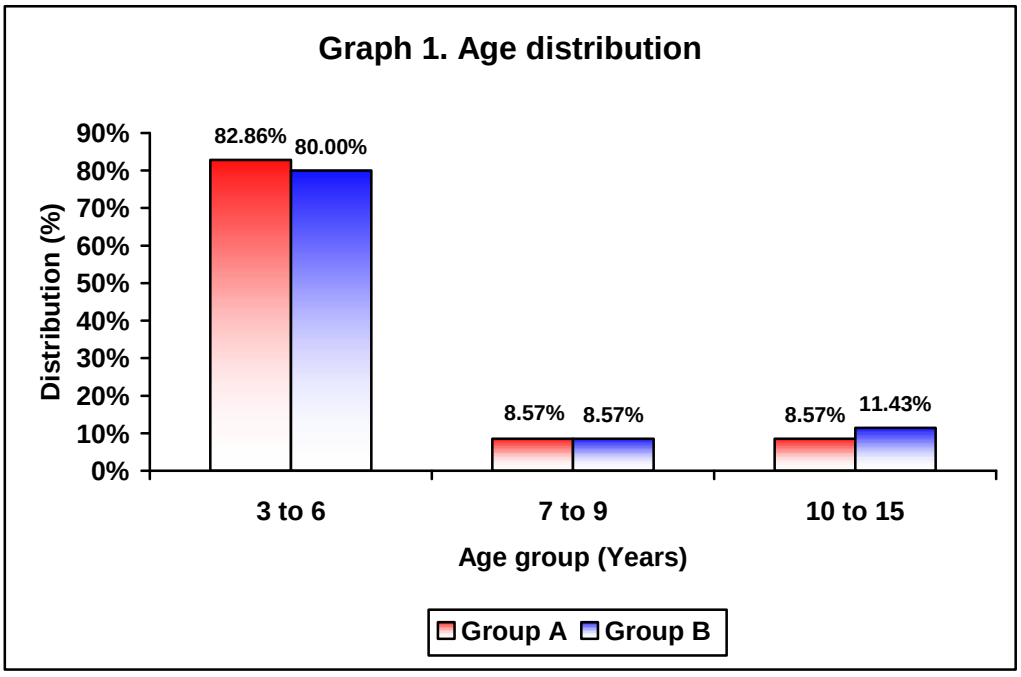
- Group B - Patients undergoing circumcision and skin approximation by cyanoacrylate tissue glue.

The data obtained was coded and entered into the Microsoft Excel Spreadsheet. The data was analysed and the final results and observations were tabulated as below.

Table 1. Age distribution

Age group (Years)	Group A (n=35)		Group B (n=35)	
	Number	**Percentage**	**Number**	**Percentage**
3 to 6	29	82.86	28	80.00
7 to 9	3	8.57	3	8.57
10 to 15	3	8.57	4	11.43
Total	**35**	**100.00**	**35**	**100.00**

p = 1.000



In the present study majority of the patients that is, 82.86% in group A and 80% in group B were in the age group of three to six years (p=1.000).

Table 2. Mean age

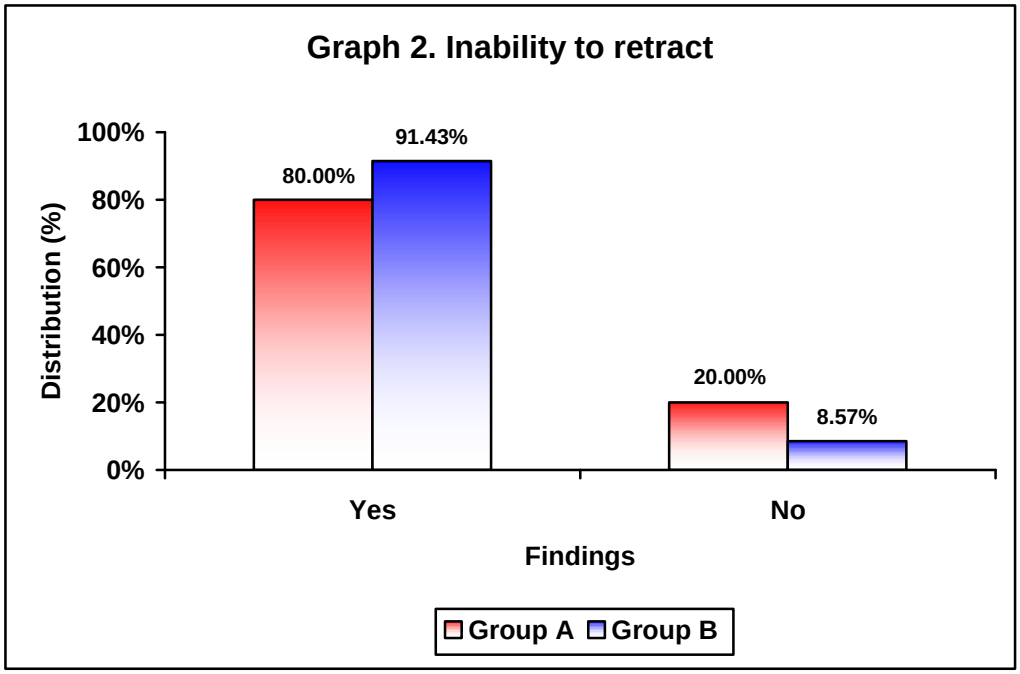
Variables	Group A (n=35)		Group B (n=35)		p value
	Mean	**SD**	**Mean**	**SD**	
Age (Years)	5.51	2.65	5.32	2.75	0.771

In this study the mean age of the study population was comparable in group A and B that is, 5.51 ± 2.65 years in group A compared to 5.32 ± 2.75 years in group B (p=0.771).

Table 3. Inability to retract

Findings	Group A (n=35)		Group B (n=35)	
	Number	**Percentage**	**Number**	**Percentage**
Yes	28	80.00	32	91.43
No	7	20.00	3	8.57
Total	**35**	**100.00**	**35**	**100.00**

p = 0.172

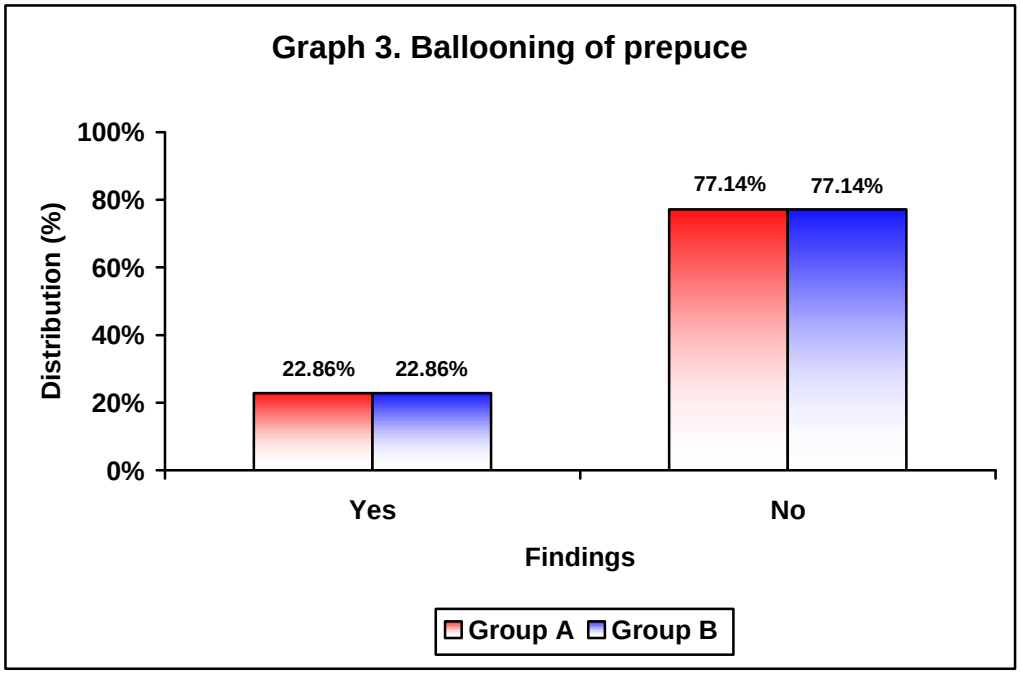


In this study 80% of the patients in group A were unable to retract the prepuce compared to 91.43% of the patients in group B. However this difference was statistically not significant (p=0.172)

Table 4. Ballooning of prepuce

Findings	Group A (n=35)		Group B (n=35)	
	Number	**Percentage**	**Number**	**Percentage**
Yes	8	22.86	8	22.86
No	27	77.14	27	77.14
Total	**35**	**100.00**	**35**	**100.00**

p = 1.000

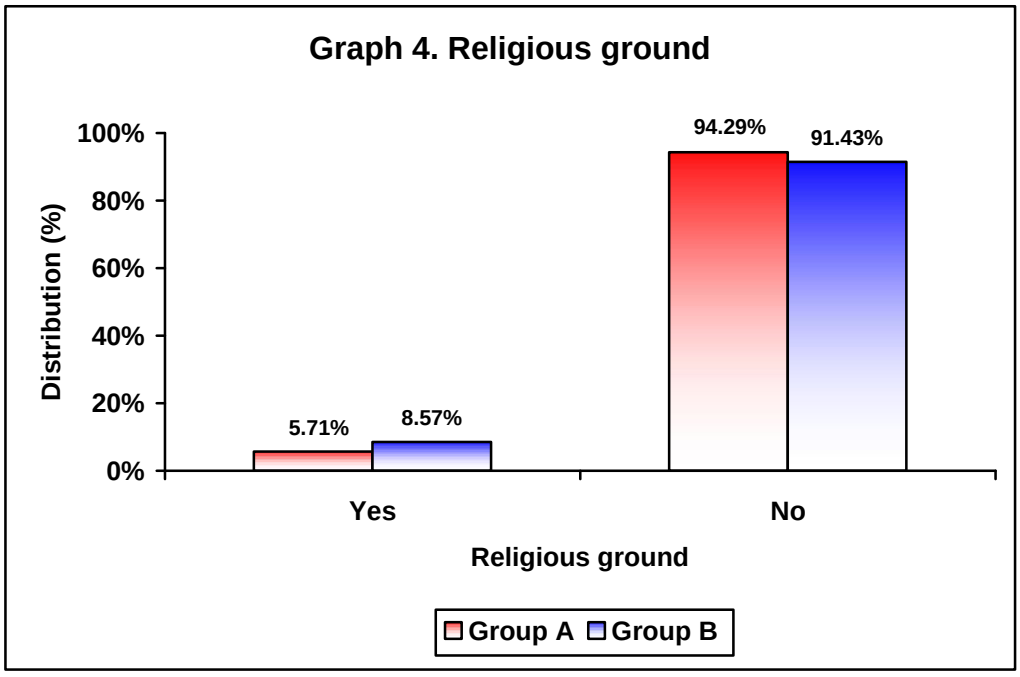


In the present study ballooning of prepuce was noted in 22.86% of the patients each in group A and B (1.000).

Table 5. Religious ground

Religious ground	Group A (n=35)		Group B (n=35)	
	Number	**Percentage**	**Number**	**Percentage**
Yes	2	5.71	3	8.57
No	33	94.29	32	91.43
Total	**35**	**100.00**	**35**	**100.00**

p = 0.673

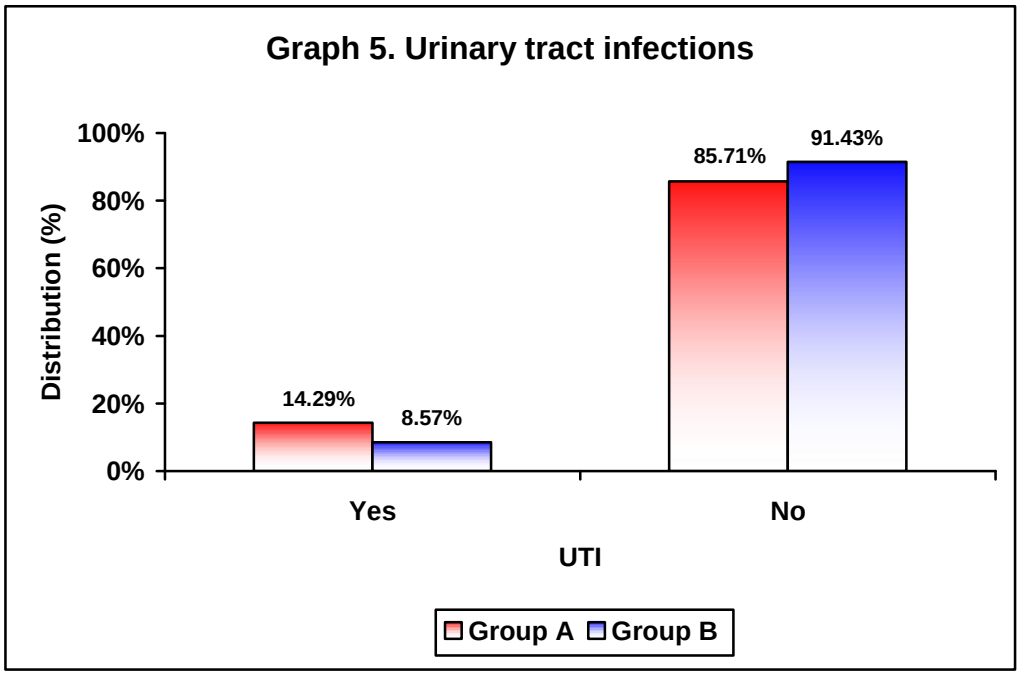


In this study 5.71% of the children in group A and 8.57% of the children in group B opted for circumcision based on religious ground. However this difference was statistically not significant (p=0.673)

Table 6. Urinary tract infections

Findings	Group A (n=35)		Group B (n=35)	
	Number	**Percentage**	**Number**	**Percentage**
Yes	5	14.29	3	8.57
No	30	85.71	32	91.43
Total	**35**	**100.00**	**35**	**100.00**

p = 0.452



In the present study 14.29% of the patients in group A had urinary tract infection compared to 8.57% of the patients in group B. However this difference was statistically not significant (p=0.452)

Table 7. Vitals

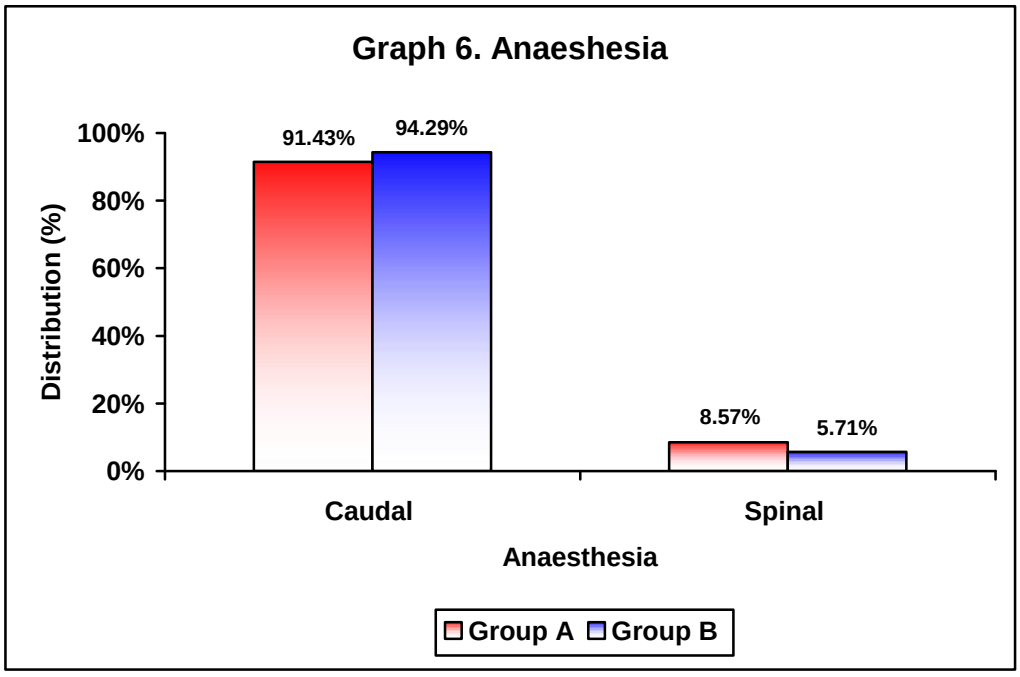
Variables	Group A (n=35)		Group B (n=35)		p value
	Mean	**SD**	**Mean**	**SD**	
Pulse rate (/Min)	98.51	9.23	98.05	10.38	0.846
Systolic BP (mm Hg)	96.62	7.58	95.60	8.80	0.602
Diastolic BP (mm Hg)	60.85	9.69	61.25	9.30	0.861
Respiratory Rate (/Min)	27.54	4.17	27.05	3.96	0.619

In this study vitals including pulse rate, systolic blood pressure, diastolic blood pressure and respiratory rate were comparable in group A and B ($p>0.050$).

Table 8. Anaesthesia

Anaesthesia	Group A (n=35)		Group B (n=35)	
	Number	**Percentage**	**Number**	**Percentage**
Caudal	32	91.43	33	94.29
Spinal	3	8.57	2	5.71
Total	**35**	**100.00**	**35**	**100.00**

p = 0.500



In the present study majority of the patients in group A (91.43%) and Group B (94.29%) had surgery under caudal plus spinal anaesthesia (p=0.500).

Table 9. Mean surgical time

Variables	Group A (n=35)		Group B (n=35)		p value
	Mean	SD	Mean	SD	
Surgical time (minute)	24.97	3.93	19.14	5.54	< 0.001

In the present study significantly lower surgical time was noted in group B compared to group A (19.14 ± 5.54 minutes vs 24.97 ± 3.93 minutes; $p<0.001$).

Table 10. Wound assessment day 3

Variables	Findings	Group A (n=35)		Group B (n=35)		p value
		No	**%**	**No**	**%**	
Redness	Present	18	51.43	15	42.86	**0.473**
	Absent	17	48.57	20	57.14	
	Total	**35**	**100.00**	**35**	**100.00**	
Tenderness	Present	30	85.71	11	31.43	**< 0.001**
	Absent	5	14.29	24	68.57	
	Total	**35**	**100.00**	**35**	**100.00**	
Oedema	Present	15	42.86	5	14.29	**0.008**
	Absent	20	57.14	30	85.71	
	Total	**35**	**100.00**	**35**	**100.00**	
Discharge	Present	8	22.86	4	11.43	**0.205**
	Absent	27	77.14	31	88.57	
	Total	**35**	**100.00**	**35**	**100.00**	

In this study during wound assessment on day three, among the patients in group A, 85.71% of patients had tenderness followed by redness (51.43%), oedema (42.86%) and discharge (22.86%). In group B the same were observed in 31.43%, 42.86%, 14.29% and 11.43% respectively. Tenderness and oedema were significantly high in group A compared to group B ($p<0.050$).

Table 11. Wound assessment day 7

Variables	Findings	Group A (n=35)		Group B (n=35)		p value
		No	**%**	**No**	**%**	
Redness	Present	11	31.43	12	34.29	**0.799**
	Absent	24	68.57	23	65.71	
	Total	**35**	**100.00**	**35**	**100.00**	
Tenderness	Present	14	40.00	8	22.86	**0.122**
	Absent	21	60.00	27	77.14	
	Total	**35**	**100.00**	**35**	**100.00**	
Oedema	Present	20	57.14	4	11.43	**< 0.001**
	Absent	15	42.86	31	88.57	
	Total	**35**	**100.00**	**35**	**100.00**	
Discharge	Present	9	25.71	2	5.71	**0.022**
	Absent	26	74.29	33	94.29	
	Total	**35**	**100.00**	**35**	**100.00**	

In this study wound assessment on day seven revealed, 57.14% of patients had oedema followed by tenderness (40%), redness (31.43%) and discharge (25.71%) in group A. In group B, the corresponding figures were 11.43%, 22.86%, 34.29% and 5.71%. The oedema and discharge were significantly high in group A compared to group B ($p<0.050$).

DISCUSSION

All the methods of circumcision require suturing and dressing. Surgical complications of male circumcision can include excessive bleeding, hematoma formation, sepsis, unsatisfactory cosmetic effect, lacerations of the penis and injury to the glans, too little or too much of foreskin excised, meatal stenosis, urinary retention, phimosis and buried penis. Among all these complications, hemorrhage and infection are the most common complications.[89]

The circumcision wound was closed by absorbable sutures, traditionally. Currently, alternative methods are being utilized to overcome the shortcomings of the conventional closure like complications, postoperative pain, time consumed and cosmetic problems. The most recent advancement is the technique of closure without sutures.[89]

In the year 1940's, variety of cyanoacrylate adhesives were developed which are series of homologous compounds known as alkyl-cyanoacrylates.[86] These glues get polymerize on contact with basic substances such as blood or water. The polymerization occurs at room temperature and does not require the use of solvent or an added catalyst. The material can be spread easily in a thin film, readily wets the surfaces to which it is applied, and produces very little heat. It should not be placed inside the wound.[89] Considering the advantages of tissue glue and scarcity of data the present study was planned to compare tissue glue approximation with conventional suture method in terms of time consumed and incidence of infection in patients undergoing circumcision.

The present one year randomized controlled trial was conducted at Department of General Surgery, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum from January 2013 to December 2013. A total of 70 patients undergoing circumcision were included in the study. Patients were divided into two groups of 35 each Randomization was done by assigning even numbers to patients in group B (skin approximation by cyanoacrylate tissue glue) and odd number to those in group A (skin approximation by suture method).

In the present study the commonest age group was three to six years comprised of 82.86% in group A and 80% in group B (p=1.000). The mean age of the study population was 5.51 ± 2.65 years in group A and in group B, it was 5.32 ± 2.75 years (p=0.771). These findings suggest that, the demographic characteristics of the study population were comparable in both the groups.

In this study the most common clinical presentation was inability to retract prepuce. In group A 80% of the patients and in group B 91.43% of the patients were unable to retract the prepuce (p=0.172). The ballooning of prepuce was present among 22.86% of the patients each in group A and B (1.000). Urinary tract infections were present in 14.29% of the patients in group A compared to 8.57% of patients in group B. (p=0.452). Few patients that is, 5.71% of children in group A and 8.57% of the children in group B were undergoing circumcision on religious ground (p=0.673). These findings indicate that presentation of the study population was comparable in both the groups.

In this study based on clinical examination findings, mean pulse rate, systolic blood pressure, diastolic blood pressure and respiratory rate were comparable in

group A and B (p>0.050). In group A, 91.43% of patients and in group B 94.29% underwent circumcision under caudal plus spinal anaesthesia (p=0.500). Hence the study population in group A and B were comparable in terms of clinical and surgical characteristics.

In the present study mean surgical time in group A was 24.97 ± 3.93 minutes compared to 19.14 ± 5.54 minutes in group B showing a difference of nearly five minutes. This difference was statistically significant (p<0.001). These findings suggest that, skin approximation by cyanoacrylate tissue glue results in significantly lower operative time compared to skin approximation by suture method. In one of the first published studies evaluating octylcyanoacrylate, Quin J et al[85] indicated that use of the skin adhesive was found to be significantly faster. Matin SF[91] and Elmore JM et al[92] also concluded that the skin adhesive technique is significantly faster. The findings of the present study were consistent with the results reported by Quin J et al[85] Martin SF[91] and Elmore JM.[92] In India, Parmar HD et al[93] used 2-octyl cyanoacrylate for closing circumcision wounds and reported that, the mean time taken for skin closure by 2-octyl cyanoacrylate is much shorter. Recently Tiwari P et al[89] in their comparative study to compare cyanoacrylate as a better alternative to conventional suture material in terms of time consumed reported mean time taken for circumcision with tissue glue as 14.2 min (SD 2.42), whereas it was 24.4 min (SD 5.06) in case of the use of sutures. The tissue glue group took 10 min shorter than the control group. Arunachalam et al.[94] showed that 2-octyl cyanoacrylate is cosmetically superior and its operative time is significantly less in comparison to suture group. In contrast, Cheng and Saing[95] concluded that tissue glue has no significant advantage over suturing and time taken was longer in tissue glue group.

Coover et al.,[86] has discovered the adhesive properties of cyanoacrylate adhesive and suggested their use as a surgical adhesive for the first time. Adhesive glue is especially useful for day care surgery like circumcision. Cyanoacrylate is a better alternative to sutures and gained increased clinical popularity due to the ease of application, decreased scarring, decreased pain and better cosmetic results with no discomfort as seen with sutures getting to or snagging the clothings and dressing.[89]

Now a day surgeons are looking for faster, comfortable and cosmetically best technique for skin closure, more over 2-octyl cyanoacrylate is easier to use and provides a flexible, water resistant, sealed skin closure. 2-0ctyl cyanoacrylate provides a needle-free method of wound closure, an important consideration because needle stick injuries are avoided.[96] It requires no bandaging due to its antimicrobial properties.[97] For the patient side, it gives less pain during post-operative period, needs no suture or staple removal, disappears naturally as incision heals, leaves no marks and patients can even have a shower.[98]

In this study wound assessment on post operative day three revealed more complications in group A compared to group B. In group A, 85.71% of patients had tenderness and 42.86% had oedema compared to 31.43% and 14.29% in group B respectively. This difference was statistically significant ($p<0.050$). Though redness and discharge were high in (51.43% and 22.86% respectively) group A compared to group B (42.86% and 11.43% respectively) the difference was statistically not significant ($p>0.050$). Similar rate of complications was noted during wound assessment on day seven that is, in group A oedema, tenderness, redness and discharge were present in 57.14%, 40%, 31.43% and 25.71% compared to 11.43%, 22.86%, 34.29% and 5.71%. However at this follow up oedema and discharge were

significantly low in group B compared to group A ($p<0.050$). These findings suggest lower rate of complications in patients who had skin approximation using cyanoacrylate tissue glue compared to suture method. Recently Tiwari P et al[89] in their comparative study reported that, tissue glue results in lower rate of wound inflammation, bleeding or hematoma rate compared to sutures. Singer AJ et al[99] reported fewer cases of adhesive glue were erythematous at the end of 1st week after surgery and wound dehiscence rate of 1.6% in adhesive glue group and 0.9% in suturing group. In Toriumi DM et al[100] they had evaluated wound at 1st week and had not observed any complication. In a study Suture less Circumcision Using 2-octly cyanoacrylate (Dermabond): appraisal after 18 months of experience by Elmore JM et al[101] no patient developed wound complication.

Overall the present study showed that, skin approximation by cyanoacrylate tissue glue significantly reduces duration of operative time and reduces rate of complications significantly compared to skin approximation by suture method.

CONCLUSION

Based on the findings of the present study it may be concluded that, skin approximation by cyanoacrylate tissue glue reduces duration of surgery and results in lower complications compared to skin approximation by suture method.

SUMMARY

Traditionally, the circumcision wound was closed by absorbable sutures. Recently the use of tissue adhesive had evoked immense interest in the field of wound healing. This study was planned to compare tissue glue approximation with conventional suture method in terms of time consumed and incidence of infection in patients undergoing circumcision.

This one year randomized controlled trial was performed on a total of 70 patients undergoing circumcision at Department of General Surgery, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum from January 2013 to December 2013. Patients were randomized by assigning even numbers to patients in group B (skin approximation by cyanoacrylate tissue glue) and odd number to those in group A (skin approximation by suture method). Patients were examined for infection and other complication on the post operative day three and seven and operative time was noted.

Majority of the patients were in the age group of three to six years (82.86% in group A and 80% in group B; p=1.000). The mean age was comparable in group A and B (5.51 ± 2.65 vs 5.32 ± 2.75 years; p=0.771). Further the clinical presentation, indications for circumcision, clinical examination findings (vitals) and surgical characteristics were comparable in group A and B (p>0.050). Surgical time in group B was significant low compared to group A with a difference of nearly more than five minutes (19.14 ± 5.54 vs 24.97 ± 3.93 minutes; p<0.001). On day three wound assessment, significantly lower rate of complications was noted among the patients with group B with regard to tenderness and oedema (p<0.050). During

day seven assessment also significantly lower number of patients had oedema and discharge in group A compared to group B ($p<0.050$).

Skin approximation by cyanoacrylate tissue glue results in significant reduction of surgical time with lower rates of complications compared to skin approximation by suture method.

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ANNEXURE I – CONSENT FORM

Mr / Mrs / Miss _____ we are requesting you to enrol yourself in study entitled, **"TISSUE GLUE AS AN ALTERNATIVE METHOD OF SKIN APPROXIMATION IN PATIENTS UNDERGOING CIRCUMCISION – A ONE YEAR RANDOMIZED CONTROLLED TRIAL AT KLES DR. PRABHAKAR KORE HOSPITAL AND MRC"** is being conducted by Dr. *** *****, Post Graduate in Surgery at Jawaharlal Nehru Medical College Belgaum, Karnataka. Under guidance of Dr. **** ****** MS, FICS Principal and Professor, Department of Surgery, Jawaharlal Nehru Medical College, Belgaum, under KLE University, Belgaum.

Respected Sir/Madam, we request you to enrol yourself to participate in our study as you are eligible for participating in this study. During the study you will be asked some questions regarding your present complaints and your are suppose to answer to the best of your knowledge.

Your participation in research is voluntary. If you decide to participate you are free to withdraw at any time.

The purpose of research is to evaluate the efficacy of tissue glue (cyanoacrylate) compared with a traditional suture (Catgut) in reducing the time consumed in circumcision and incidence of infection.

Procedure involved

If you agree to enroll yourself in this study, you will be informed in detail about the procedure. You will be interviewed regarding your present, past and

family history then you will be clinically examined in detail and investigated accordingly. Computer generated block random number will be used to assign the type of procedure to the patients is, control group or study group. If you are in control group suture will be used and if you are in study group cyanoacrylate tissue glue will be used. The time consumed will be assessed for both groups of participants and the site of approximation of skin will be assessed on post operative day five and seven.

Benefits and Risks

The benefits of taking part in this research are you will have reduced surgical procedure time and post surgical site infection. There no observable risks associated with this study.

Voluntary participation / Withdrawal

Taking part in the study is voluntary. You may choose not to enrol yourself in this study. Your decision will not change present or future health care services offered to you at KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum.

Alternatives

Even if you decline the participation in the study, you will get the routine line of management.

Privacy and confidentiality

The only people to know that you are a research subject are members of the

research team. No information about you or information provided by you during the research will be disclosed to other without your written permission except in emergency to protect your rights and welfare or if required by law.

Authorization to Publish Results

When the results of the research are published or discussed, in a conference, no information will be displayed that would disclose your identity. Any information that is obtained in connection with this study and that can be identified with you will remain confidential.

Financial Incentives for participation

No financial incentives are being offered to enrolled patients. It is purely being done with the idea of research and all the cost of the study will be borne by the investigator.

Compensation

In the event of injury, related to the study, treatment will be made available at KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum. There is compensation or payment for such medical treatment by law.

Questions/Contact details

If you have any queries, in future or in case of study related injury or illness, you may contact. Dr. **** ****** at Department of Surgery, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum Phone Number **** ***** or on **** ******.

If you have any queries about your rights as a study subject, you may call Dr. **** ****** MS, FICS Principal and Guide, J. N. Medical College Institutional Ethical Committee for Human Subjects Research, Ph. *** ****** at J. N. Medical College, Belgaum.

CONSENT TO PARTICIPATE IN A RESEARCH STUDY:

I, Mr./Mrs. _____

voluntarily agree to take part in this study, by signing this consent form I am not giving up my legal rights. I may withdraw at any time. I am signing after having read, or been read to me in the vernacular language including risks and the benefits and having all queries cleared.

Subject Name: _____

Signature of the participant _____ Date _____
Or Left thumb print

Witness name: _____

Signature: _____ Date _____

Investigator's name: _____

Signature: _____ Date _____

Place: _____

CONSENT FORM FOR CHILDREN

Mr / Mrs / Miss _____ we are requesting you to enrol yourself in study entitled, **"TISSUE GLUE AS AN ALTERNATIVE METHOD OF SKIN APPROXIMATION IN PATIENTS UNDERGOING CIRCUMCISION – A ONE YEAR RANDOMIZED CONTROLLED TRIAL AT KLES DR. PRABHAKAR KORE HOSPITAL AND MRC"** is being conducted by Dr. ***** *******, Post Graduate in Surgery at Jawaharlal Nehru Medical College Belgaum, Karnataka. Under guidance of Dr. **** ***** Principal and Professor, Department of Surgery, Jawaharlal Nehru Medical College, Belgaum, under KLE University, Belgaum.

Respected Sir/Madam, we request you to enrol your child to participate in our study as your child is eligible for participating in this study. During the study you / your child will be asked some questions regarding his present complaints and you / your child are suppose to answer to the best of your knowledge.

Participation of your child in research is voluntary. If you decide you child to participate you are free to withdraw at any time.

The purpose of research is to evaluate the efficacy of tissue glue (cyanoacrylate) compared with a traditional suture (Catgut) in reducing the time consumed in circumcision and incidence of infection.

Procedure involved

If you agree to enrol your child in this study, you will be informed in detail about the procedure. You will be interviewed regarding your child's present, past

and family history then your child will be clinically examined in detail and investigated accordingly. Computer generated block random number will be used to assign the type of procedure to the patients is, control group or study group. If your child is in control group suture will be used and if your child is in study group, cyanoacrylate tissue glue will be used. The time consumed will be assessed for both groups of participants and the site of approximation of skin will be assessed on post operative day five and seven.

Benefits and Risks

The benefits of taking part in this research are your child will have reduced surgical procedure time and post surgical site infection. There no observable risks associated with this study.

Voluntary participation / Withdrawal

Taking part in the study is voluntary. You may choose not to enrol your child in this study. Your decision will not change present or future health care services offered to your child at KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum.

Alternatives

Even if you decline the participation of your child in the study, your child will get the routine line of management.

Privacy and confidentiality

The only people to know that your child is a research subject are members of

the research team. No information about your child or information provided by you during the research will be disclosed to other without your written permission except in emergency to protect your child's rights and welfare or if required by law.

Authorization to Publish Results

When the results of the research are published or discussed, in a conference, no information will be displayed that would disclose your child's identity. Any information that is obtained in connection with this study and that can be identified with your child will remain confidential.

Financial Incentives for participation

No financial incentives are being offered to enrolled patients. It is purely being done with the idea of research and all the cost of the study will be borne by the investigator.

Compensation

In the event of injury, related to the study, treatment will be made available at KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum. There is compensation or payment for such medical treatment by law.

Questions/Contact details

If you have any queries in future or in case of study related injury or illness, you may contact. Dr. **** ***** at Department of Surgery, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum Phone Number **** ****** or on **** *****.

If you have any queries about your child's rights as a study subject, you may call ***** ******* Principal and Guide, J. N. Medical College Institutional Ethical Committee for Human Subjects Research, Ph. **** ****** at J. N. Medical College, Belgaum.

CONSENT TO PARTICIPATE IN A RESEARCH STUDY:

I, Mr./Mrs. _____

voluntarily agree my child to take part in this study, by signing this consent form I am not giving up my legal rights. I may withdraw at any time. I am signing after having read, or been read to me in the vernacular language including risks and the benefits and having all queries cleared.

Subject Name: _____

Signature of the participant _____ Date _____
Or Left thumb print

Witness name: _____

Signature: _____ Date _____

Investigator's name: _____

Signature: _____ Date _____

Place: _____

ANNEXURE II – PROFORMA

"TISSUE GLUE AS AN ALTERNATIVE METHOD OF SKIN APPROXIMATION IN PATIENTS UNDERGOING CIRCUMCISION"

Investigator: **Dr. ***** *******
Post Graduate Student,
Department of Surgery,
J. N. Medical College, Belgaum

Name of the Guide: **Dr. ***** *******

PATIENT IDENTIFICATION DATA

Group	:	Case No.	:
IP No	:	DOA	:
Name	:	DOS	:
Sex	:	DOD	:
Age	:	Caste	:
Address	:		

CHIEF COMPLAINTS

Inability to retract perpuce	Yes/No
Ballooning of perpuce	Yes/No
Religious ground	Yes/No
Any other:	

MEDICAL HISTORY

Diabetes mellitus	:
Immunocompromised state	:

GENERAL PHYSICAL EXAMINATION

Pulse Rate : /Min B.P. : mm Hg

Temperature : ^{0}F R. R. : /Min

Systemic Examination

Respiratory :

CVS :

CNS :

Local examination

INVESTIGATIONS

CBC :

Blood grouping :

Bleeding time :

Clotting time :

PT / INR :

Blood urea :

Serum creatinine :

OPERATION DETAILS

Date of surgery :

Anaesthesia :

Procedure done :

Duration of surgery :

Assessment of Wound

Outcome :

ANNEXURE III – KEY TO MASTER CHART

-	-	Absent
+	-	Present
A	-	Group A
B	-	Group B
BP	-	Blood pressure
bpm	-	Beats per minute
CA+IV	-	Caudal anaesthesia with intravenous sedation
mm Hg	-	Millimeters of mercury
NAD	-	No abnormality detected
SA	-	Spinal anaesthesia
UTI	-	Urinary tract infection

ANNEXURE III - MASTER CHART

Serial Number	In patient number	Group	Age (Years)	Chief complaints				Medical history	Clinical examination					Surgery details		Wound assessment							
										BP						Day 3				Day 7			
				Inability to retract	Ballooning of perpuce	Religious ground	Other		Pulse rate (bpm)	Systolic (mm Hg)	Diastolic (mm Hg)	Respiratory rate (bpm)	Systemic examination	Anasesthesia	Duration (Minutes)	Redness	Tenderness	Oedema	Discharge	Redness	Tenderness	Oedema	Discharge
1	547326	A	14	+	-	-	-	-	76	96	68	18	NAD	SA	36	+	+	+	+	+	+	+	+
2	568972	B	4	+	-	-	-	-	100	80	50	32	NAD	CA+IV	35	+	+	+	+	+	+	+	+
3	578691	A	4	+	-	-	-	-	102	92	50	24	NAD	CA+IV	28	-	+	-	-	-	-	+	-
4	568260	B	3	+	-	-	-	-	104	94	54	30	NAD	CA+IV	32	+	+	+	+	+	+	+	+
5	514207	A	6	+	-	-	-	-	90	102	68	30	NAD	CA+IV	25	-	+	-	-	-	-	+	-
6	542323	B	3	+	-	-	-	-	100	86	54	28	NAD	CA+IV	30	+	+	+	-	+	+	-	-
7	515122	A	7	-	+	-	-	-	112	110	78	32	NAD	CA+IV	21	+	+	+	-	-	+	+	-
8	548931	B	6	+	-	-	-	-	88	102	70	24	NAD	CA+IV	28	-	-	-	-	-	-	-	-
9	567134	A	6	+	+	-	-	-	86	98	62	30	NAD	CA+IV	28	-	+	-	-	-	-	-	-
10	567892	B	3	+	-	-	-	-	106	100	60	24	NAD	CA+IV	24	+	+	-	-	+	+	-	-
11	564680	A	4	+	-	-	-	-	106	98	54	30	NAD	CA+IV	30	+	+	-	-	-	-	-	-
12	520679	B	4	+	-	-	-	-	102	80	52	24	NAD	CA+IV	22	+	-	-	-	+	-	-	-
13	567280	A	5	-	-	+	-	-	100	86	52	28	NAD	CA+IV	27	-	+	+	-	-	-	-	-
14	521046	B	7	-	-	+	-	-	98	106	72	22	NAD	CA+IV	20	-	-	-	-	-	-	-	-
15	522067	A	7	-	-	+	-	-	96	104	70	26	NAD	CA+IV	27	-	+	-	-	-	-	+	-
16	524443	B	3.4	+	-	-	UTI	-	102	96	54	30	NAD	CA+IV	18	+	-	-	-	-	-	-	-
17	534213	A	3.4	+	-	-	-	-	104	92	52	26	NAD	CA+IV	24	+	+	+	+	+	+	+	+
18	589640	B	3	+	-	-	-	-	108	102	62	26	NAD	CA+IV	15	-	-	-	-	-	-	-	-
19	568321	A	4.6	+	-	-	-	-	108	102	64	32	NAD	CA+IV	29	+	+	+	+	+	+	+	+
20	546284	B	3	+	-	-	-	-	102	88	48	30	NAD	CA+IV	18	-	-	-	-	-	-	-	-
21	528532	A	3	+	-	-	-	-	100	90	48	34	NAD	CA+IV	29	-	-	-	-	-	-	-	-
22	518532	B	4	+	+	-	-	-	102	92	50	24	NAD	CA+IV	15	-	-	-	-	-	-	-	-

ANNEXURE III - MASTER CHART

Serial Number	In patient number	Group	Age (Years)	Chief complaints				Medical history	Clinical examination					Surgery details		Wound assessment							
										BP						Day 3				Day 7			
				Inability to retract	Ballooning of perpuce	Religious ground	Other		Pulse rate (bpm)	Systolic (mm Hg)	Diastolic (mm Hg)	Respiratory rate (bpm)	Systemic examination	Anasesthesia	Duration (Minutes)	Redness	Tenderness	Oedema	Discharge	Redness	Tenderness	Oedema	Discharge
23	528551	A	4	+	+	-	-	-	110	104	68	30	NAD	CA+IV	30	-	-	-	-	-	-	-	-
24	528665	B	6	-	-	+	-	-	96	102	72	26	NAD	CA+IV	16	+	+	-	-	-	-	-	-
25	529123	A	6	+	+	-	-	-	98	104	70	30	NAD	CA+IV	29	+	+	+	+	+	+	+	+
26	529778	B	4	+	-	-	-	-	102	86	56	24	NAD	CA+IV	20	+	-	-	-	+	-	-	-
27	529814	A	4	+	+'	-	UTI	-	100	88	50	30	NAD	CA+IV	23	+	+	+	+	+	+	+	+
28	529912	B	4	+	-	-	-	-	106	98	56	34	NAD	CA+IV	14	-	-	-	-	-	-	-	-
29	563190	A	5	+	-	-	-	-	102	80	50	28	NAD	CA+IV	21	+	+	+	+	+	+	+	+
30	534564	B	6	+	+	-	UTI	-	110	110	76	26	NAD	CA+IV	30	+	-	-	-	+	+	-	-
31	564630	A	4	+	-	-	-	-	106	96	52	30	NAD	CA+IV	24	+	+	+	+	+	+	+	-
32	535066	B	8	+	-	-	-	-	80	108	72	20	NAD	CA+IV	14	-	-	-	-	-	-	-	-
33	535005	A	4	+	-	-	+	-	102	92	50	24	NAD	CA+IV	20	-	+	-	-	-	-	-	-
34	536123	B	4	+	-	-	UTI	-	100	82	52	29	NAD	CA+IV	15	-	-	-	-	-	-	-	-
35	536857	A	5	+	-	-	-	-	102	86	50	24	NAD	CA+IV	28	-	-	-	-	-	-	-	-
36	538417	B	12.1	-	-	+	-	-	78	98	72	30	NAD	SA	15	+	+	+	+	+	+	+	-
37	544227	A	6	+	-	-	-	-	96	102	70	20	NAD	CA+IV	25	-	-	-	-	-	-	-	-
38	544224	B	10	+	+	-	-	-	80	106	76	30	NAD	SA	17	-	+	-	-	-	+	-	-
39	545428	A	6	-	+	-	UTI	-	102	110	76	24	NAD	CA+IV	26	+	+	+	-	+	+	+	+
40	548364	B	3	+	-	-	-	-	102	94	52	26	NAD	CA+IV	20	+	+	+	+	+	+	+	-
41	546580	A	3	+	-	-	-	-	100	80	56	28	NAD	CA+IV	24	-	+	-	-	-	-	-	-
42	546486	B	5	+	-	-	-	-	106	102	66	26	NAD	CA+IV	16	-	-	-	-	-	-	-	-
43	547326	A	14	-	+	-	-	-	80	102	70	24	NAD	SA	22	+	+	+	-	-	+	+	-
44	559661	B	6	+	-	-	-	-	98	108	74	30	NAD	CA+IV	18	-	-	-	-	-	-	-	-

ANNEXURE III - MASTER CHART

Serial Number	In patient number	Group	Age (Years)	Chief complaints				Medical history	Clinical examination					Surgery details		Wound assessment							
										BP						Day 3				Day 7			
				Inability to retract	Ballooning of perpuce	Religious ground	Other		Pulse rate (bpm)	Systolic (mm Hg)	Diastolic (mm Hg)	Respiratory rate (bpm)	Systemic examination	Anasesthesia	Duration (Minutes)	Redness	Tenderness	Oedema	Discharge	Redness	Tenderness	Oedema	Discharge
45	549102	A	5	+	-	-	UTI	-	104	92	52	32	NAD	CA+IV	28	-	+	-	-	-	-	-	-
46	546580	B	5	+	+	-	-	-	102	94	56	30	NAD	CA+IV	17	-	-	-	-	-	-	-	-
47	550340	A	3	+	-	-	UTI	-	102	90	52	24	NAD	CA+IV	27	-	+	-	-	-	-	-	-
48	550249	B	4	+	-	-	-	-	104	86	54	28	NAD	CA+IV	13	+	-	-	-	+	-	-	-
49	550340	A	4	+	-	-	-	-	104	96	56	34	NAD	CA+IV	28	+	+	+	-	-	-	+	+
50	550249	B	3	+	+	-	-	-	104	92	52	24	NAD	CA+IV	16	+	+	-	-	-	-	-	-
51	550671	A	6	+	-	-	-	-	88	98	68	20	NAD	CA+IV	19	-	+	-	-	-	-	+	-
52	551452	B	4	+	+	-	-	-	104	94	54	24	NAD	CA+IV	15	-	-	-	-	-	-	-	-
53	552529	A	4	+	-	-	-	-	108	100	60	30	NAD	CA+IV	21	+	+	+	-	-	+	+	-
54	547219	B	4	+	-	-	-	-	104	98	58	34	NAD	CA+IV	18	+	+	-	-	+	-	-	-
55	555337	A	4	-	+	-	-	-	106	94	56	24	NAD	CA+IV	19	-	+	-	-	-	-	-	-
56	556809	B	12	+	-	-	-	-	70	92	62	18	NAD	CA+IV	22	-	-	-	-	-	-	-	-
57	557824	A	4.1	+	-	-	-	-	106	98	52	30	NAD	CA+IV	20	-	+	-	-	-	-	-	-
58	557753	B	4	+	-	-	-	-	108	104	66	32	NAD	CA+IV	19	-	-	-	-	-	-	-	-
59	567141	A	6	-	-	-	-	-	90	102	72	32	NAD	CA+IV	22	+	+	+	-	+	+	+	-
60	559748	B	8	+	-	-	-	-	80	100	78	24	NAD	CA+IV	17	+	+	-	-	+	-	-	-
61	560134	A	4	+	-	-	-	-	104	100	60	28	NAD	CA+IV	27	-	+	-	-	-	-	-	-
62	560336	B	3	+	-	-	-	-	110	106	70	34	NAD	CA+IV	18	-	-	-	-	-	-	-	-
63	560337	A	3	+	-	-	-	-	102	88	52	34	NAD	CA+IV	20	+	+	-	-	-	-	+	-
64	562313	B	13	+	+	-	-	-	78	98	72	22	NAD	CA+IV	16	-	-	-	-	-	-	-	-
65	563278	A	9	+	-	-	-	-	80	104	78	22	NAD	CA+IV	21	+	+	+	+	+	+	+	+
66	563059	B	5	+	+	-	-	-	100	80	54	26	NAD	CA+IV	15	-	-	-	-	-	-	-	-

ANNEXURE III - MASTER CHART

Serial Number	In patient number	Group	Age (Years)	Chief complaints				Medical history	Clinical examination					Surgery details		Wound assessment							
										BP						Day 3				Day 7			
				Inability to retract	Ballooning of perpuce	Religious ground	Other		Pulse rate (bpm)	Systolic (mm Hg)	Diastolic (mm Hg)	Respiratory rate (bpm)	Systemic examination	Anasesthesia	Duration (Minutes)	Redness	Tenderness	Oedema	Discharge	Redness	Tenderness	Oedema	Discharge
67	564952	A	10	+	-	-	-	-	80	106	76	26	NAD	SA	22	+	+	-	-	-	+	+	-
68	565360	B	4	+	-	-	-	-	102	82	52	30	NAD	CA+IV	16	-	-	-	-	-	-	-	-
69	523605	A	6	+	-	-	-	-	96	100	68	26	NAD	CA+IV	24	+	-	-	-	+	-	-	-
70	589271	B	6	+	-	-	-	-	96	100	66	26	NAD	CA+IV	16	-	-	-	-	-	-	-	-