"A ONE YEAR RANDOMIZED CONTROL STUDY TO COMPARE THE OUTCOMES OF PERIANAL SURGERY WOUNDS WHEN USING SILVER COLLOIDAL SOLUTION SPRAY Vs. POVIDONE IODINE SITZ-BATH AT KLES DR. PRABHAKAR KORE HOSPITAL"

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REG NO.BH0118012

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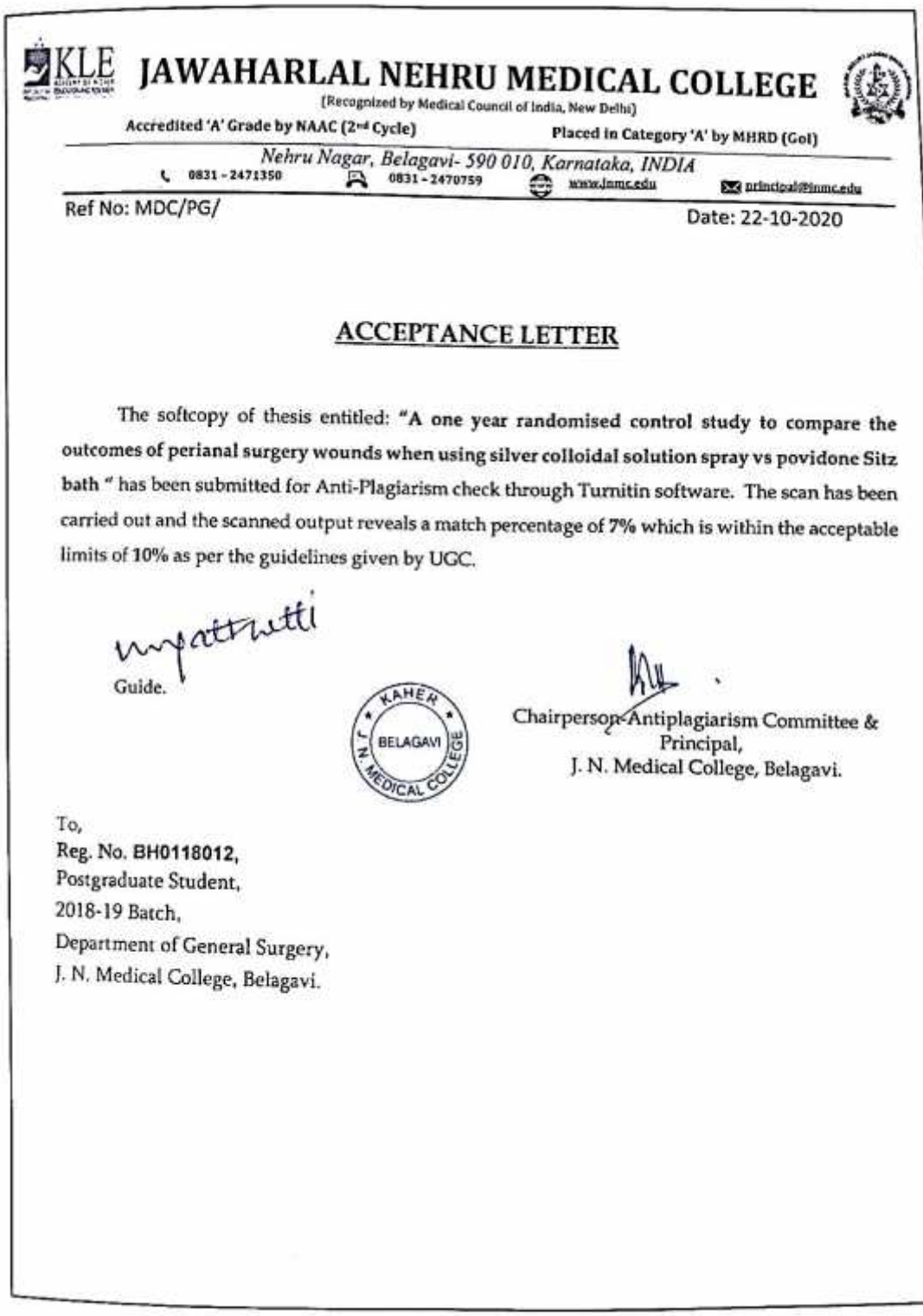

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ABBREVIATIONS

AgNP's	-	Silver Nanoparticles
USG.	-	Ultrasonography
MRI	-	Magnetic Resonance Imaging
CT	-	Computed tomography
HIV	-	Human immunodeficiency virus
HBsAg	-	Hepatitis B surface antigen
vs	-	Versus
R/S	-	Respiratory system
CVS	-	Cardiovascular system
P/A	-	Per Abdomen
WBC	-	White blood cells
TLC	-	Total Leukocyte Count
DLC	-	Differential Leukocyte Count
ECG	-	Electrocardiogram

ABSTRACT

TITLE: - "A ONE YEAR RANDOMIZED CONTROL STUDY TO COMPARE THE OUTCOMES OF PERIANAL SURGERY WOUNDS WHEN USING SILVER COLLOIDAL SOLUTION SPRAY vs. POVIDONE IODINE SITZ-BATH AT KLES DR. PRABHAKAR KORE HOSPITAL"

INTRODUCTION: -

Anorectal diseases are the group of disorders that arise at the juncture of rectum and anal canal. The commonly describedbenign anorectal disorders include Haemorrhoids, Anorectal Abscess, Fissure-in-Ano, and Fistula-in-Ano. These disorders have been treated by surgical interventions like Haemorrhoidectomy, Incision and Drainage, Fissurectomy, Fistulectomy etc. These wounds are usually not sutured and are kept open due to their proximity to the anal opening and thus, very high chances of infection.

Sitz-Bath has been frequently recommended by physicians for a variety of post-perianal surgical wounds. Sitz-Bath is efficacious in relieving pain.Healing occurs due to the antiseptic properties of povidone iodine which is used as an additive to the Sitz-bath.

Privacy, need for a sitz-bath tub or a flat bucket and multiple sittings every day decrease the Sitz-bath usage in the majority of low socioeconomic population due to the inconvenience, lack of privacy and lack of time, which may ultimately lead to non-compliance and improper wound healing.

In spray form, the silver colloidal solution has been in use primarily for the ulcerative superficial wounds for the purpose of healing e.g. Diabetic foot ulcers,

Bedsores, Debrided post-operative wounds of extremities, Surgical site infection wounds etc.

Apart from its antiseptic property, it also acts as a washing agent and due to this quality, it could be used for the post-operative perianal surgical wounds for healing. In this study we want to assess the novel approach of silver spray application over these perianal wounds and the superiority in terms of less time consumptionand convenience to the patient as it would not require the tedious procedure of taking a sitz-bath as the patients could spray the wound as per their convenience. The ease of application with the spray formulation is another benefit as it doesn't command the patient towards the inconvenience of exclusive privacy which is required for taking a sitz-bath.

AIMS AND OBJECTIVES:-

- **Primary objective** of this randomized trial was to clinically assess the efficacy of Silver Colloidal Solution Spray vs. Povidone Iodine Sitz-Bath in the post-operative wound healing in the patients undergoing fissurectomy, fistulectomy and perineal abscess surgeries.
- **Secondary objectives** for the study were to compare the:
    1. Post-operative Decrease in Pain.
    2. Convenience to the patients.
    3. Compliance of the patient towards the Procedure.

Among the patients who're undergoing fissurectomy, fistulectomy and perineal abscess surgeries.

MATERIALS AND METHODS: -

A Hospital based one year Randomized Controlled Trial Study was conducted in the Department of General surgery, KLE'S Dr.Prabhakar Kore Hospital and Medical Research Centre, Belagavi from 1st January 2019to 31st December 2020 and required data was collected from 68 patients who went through perianal surgical procedures and all patients were assessed using VAS Score and Likert Scales to evaluate the efficacy of both scoring systems.

RESULTS: -

In a study of 68 patients of operated perianal wounds, males comprised (73.53%) and females (26.47%). Maximum patients belong to the age group of 20 to 29 years.

Pain in perianal region was the most common symptom followed by swelling in the perianal region and discharge from the perianal region respectively.

Majority of patients were in operated for Fistula in ano (35.29%), followed by Perianal abscess (32.35%), fissure in ano (30.88%) and Fistula with Fissure in ano (1.47%).

It is found that the Silver spray application for postoperative perianal surgical wounds is significantly superior to the conventional method of sitz bath, as:

1. Silver spray application leads to faster healing rates.
2. Patients receiving silver spray had lower average pain scores.
3. Application of silver spray was way more convenient to the patients as compared to the tedious task of performing a sitz bath.
4. The patient compliance was far better with silver spray.

CONCLUSION:-

Perianal surgical wounds have a much better healing rate in terms of the faster epithelisation of the wound surface with the use of topical colloidal silver spray when compared to povidone iodine sitz-bath. Also the colloidal silver solution is superior to the sitz bath in terms of the Post-operative pain reduction, Patient compliance as well as the convenience to the patient in the post-operative period.

KEYWORDS:-

Fissure in ano, Fistula in ano, Perianal abscess, Sitz Bath, Colloidal silver spray, Silver Nanoparticles

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INTRODUCTION

Perianal pathologies viz. fissure in ano, fistula in ano and perianal abscess amongst others are a commonly observed category of diseases in the Indian clinical scenario which require surgical intervention for their management.

These include, fissurectomy/lateral sphincterotomy for fissures, fistulectomy for fistula in ano, and incision and drainage for perianal abscess.

In the post-operative period, these conditions lead to significant morbidity to the patients, due to the procedures requiring the wound to be left open instead of being sutured, which persists till a complete healing of the surgical wound is achieved.

Till now, the most common method of post-operative management, besides regular dressings, has been a sitz bath. It is a procedure which is done by the patient thrice a day in conjunction with the regular dressings by the medical personnel.[1]

The process of taking a sitz bath involves taking warm water in a flat bucket, adding antiseptic agent e.g. povidone iodine solution and submerging the perineal region into the bucket for a significant amount of time. This method, sometimes with modifications like adding sodium bicarbonate or povidone iodine, has been the only go-to procedure for healing and pain relief in the patients operated for the said procedures.[2]

With the advents and progress in the medical science and the invention of newer compounds, Colloidal silver has been devised into a spray form containing Silver Nanoparticles which are said to be highly efficacious in preventing infection as well as killing bad pathogens.[3] The colloidal silver ointments and sprays are primarily being used for ulcerative superficial wounds for the purpose of healing e.g. Diabetic

foot ulcers, Bedsores, Debrided post-operative wounds of extremities, Surgical site infection wounds etc.[4]

The spray, packaged in a small bottle, is available in the market for application over various types of superficial wounds of the body such as various types of ulcers, operated wounds etc. It could be more convenient and beneficial for the patient to apply a silver spray as compared to the laborious process of sitz-bath.

In this study, our purpose is to determine the efficacy of the silver colloidal spray in terms of wound healing as well as the pain relief, convenience and compliance of the procedure compared to the conventional method of povidone iodine sitz bath.

AIMS AND OBJECTIVES

Primary objective of this randomized trial is to clinically assess the efficacy of Silver Colloidal Solution Spray vs. Povidone Iodine Sitz-Bath in the post-operative wound healing in the patients undergoing fissurectomy, fistulectomy and perineal abscess surgeries.

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REVIEW OF LITERATURE

A knowledge of the perineal region, its boundaries, surface marking, and its contents is of utmost importance in order to define any perineal pathology by its location.

ANATOMY[5]

Perineum is the distal region of the pelvis which is present between the thighs. Its superior border is marked by the pelvic diaphragm which separates it from the cavity of pelvis.

Perineum has structures that support the **urogenital** and gastrointestinal systems. Therefore it has an important role in micturition, defecation, sexual intercourse and childbirth.

Boundaries

It resembles a trapezium like structure, between both the thighs.

The bony margins depict the **anatomical borders**, whereas the surface anatomy of the perineum is described by the surface borders.

Anatomical Borders

The anatomical borders of the perineum are:

- Symphysis Pubis **anteriorly**.
- Coccygeal tip **posteriorly.**
- Inferior ischio-pubic rami **laterally**.
- Pelvic diaphragm **superiorly.**
- Perianal skin as the **base**.

Surface Borders

The surface marking of this region is elicited in a position with abducted lower limbs and is described as:

- **Anteriorly** –Mons in females, Penis base in males.
- **Laterally** – Medial margins of thigh.
- **Posteriorly** – Superior most part of the natal/gluteal cleft.

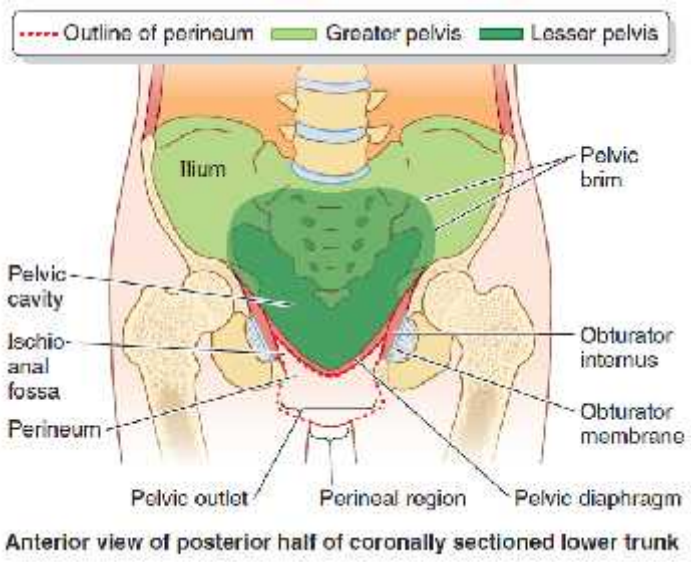


Fig 1. Perineum and perineal region.

Contents

An imaginary line drawn transversely in-between the ischial tuberosities separates the two triangles of the perineal region, the Urogenital Triangle anteriorly and the Anal Triangle posterior to it.

Anal Triangle

It constitutes the retral half of the perineum.

The main contents of the anal triangle are:

- **Aperture of the anus**.

- **External anal sphincter muscle** – voluntary muscle responsible for opening and closing the anus.

- **Ischioanal fossae** – areas situated lateral to the anus.

The **Pudendal Nerve** is a vital structure which is present inside this region. The whole of perineum derives its sensory supply from this nerve.

Urogenital Triangle

This triangle describes the anterior part of the region. The external genitalia of the body along with the urethra are the major components of this triangle.

This triangle is formatively complex, consisting of many fascial pouches and layers. The perineal membrane is a very resilient layer of the deep fascia which is present in this triangle, in addition, unlike the anal triangle which is devoid of it. The pouches are present above and below with respect to this membrane.

Superficial to Deep, the layers of urogenital triangle are:

- **Deep perineal pouch** – Enclosed by the perineal membrane below, and the deep fascia of the pelvic floor above, in females, it accommodates the vagina, external urethral sphincter and part of the urethra. In males, besides the same as present in the females, it also incorporates the deep transverse perineal muscles and the bulbourethral glands.

- **Perineal membrane** – it is a very resilient and tenacious layer of deep fascia which is pierced by the vagina in females and the urethra in males. The function is to lend support as well as attachment to the external genitalia muscles.

- **Superficial perineal pouch** – Enclosed by the perineal membrane above, and the superficial perineal fascia below, it accommodates the erectile components of the penis and clitoris, along with the bulbospongiosus, ischiocavernosus and superficial transverse perineal muscles – the three muscles in the males. Bartholin's glands are also a component of this pouch. Perineal body is the posterior-most boundary here.
- **Perineal fascia** – it's the continuation of the fascia of abdomen and is divided into:

    - Deep fascia: Encloses the penis/clitoris and the superficial perineal muscles.
    - Superficial fascia is composed of a further two layers of fascia:
        - Superficial layer – continuation of the camper's fascia of the abdominal wall.
        - Deep layer (Colles' fascia) – continuation of the scarpa's fascia of the anterior abdominal wall.

- **Skin** – The orifices of the vagina and urethra open out at the skin.

ISCHIOANAL FOSSAE

Boundaries of the ischioanal fossa are:

1. The apex is formed by the decussating fibers of the levator ani muscles and the obturator internus: these are the condensed fibers of the medial aspect of the parietal pelvic fascia covering the obturator internus muscle, named arcus tendineus of the

endopelvic fascia, on which the ileococcygeus portion of the levator ani muscle inserts. The sacrospinous ligament delimits the lateral-posterior aspect.

2. The base is oriented inferiorly and posteriorly; it is delimitated by the gluteus maximus muscle and the sacrotuberous ligament, the coccyx, the anococcygeal raphe, the external anal sphincter, the posterior margin of the superficial perineal fascia and the posterior border of the transversussuperficialis muscle of the perineum.

3. The floor is the skin of the posterior quadrants of the perineum limited by the ischial tuberosities and the coccyx and separated by the anococcygeal raphe.

4. The roof comprises the inferior fascia covering the levator ani muscle.

5. The pyramid wall comprises the puborectalis muscle and the pubococcygeal muscle covering the anal canal, and the external anal sphincter.

6. The lateral wall is formed by the medial aspect of the obturator fascia, the ischial tuberosity, and the obturator internus muscle. The fascia covering the lateral wall duplicates to form the canal in which the pudendal vessels run. The sacrotuberous ligament inserts on the ischial tuberosity, it blends the fibers with the tendon of the biceps femoris muscle and continues to the inferior pubic angle as the falciform ligament.

The ischioanal fossa anteriorly continues to the pubic bones between the muscular layers and the fascia of the levator ani muscle above and the deep transverse perineal muscle and the compressor urethra muscle below, running laterally to the urogenital organs. As a result, the fatty space assumes a wedge-shape around the portion of the pelvic viscera under the levator ani muscle, from the pubis to the coccyx.

The contents of the ischioanal fossa include the following structures, all prone to lesions or compression:

1. Internal pudendal artery, vein, and nerve.
2. Inferior rectal artery and vein
3. Inferior rectal nerve
4. Posterior scrotal vessels and nerves
5. Perineal branch of S4 and perforating cutaneous nerve
6. Lymphatics
7. Subcutaneous fat is abundant on both sides of the anal canal which permits distension of the anal canal during defecation.

The different adipose tissue around the anal canal and into the ischioanal fossa could help the tone of the plate of the levator ani muscle to balance the gradient pressures of the different intra-and extra-peritoneal spaces of abdomen, pelvis, and perineum.

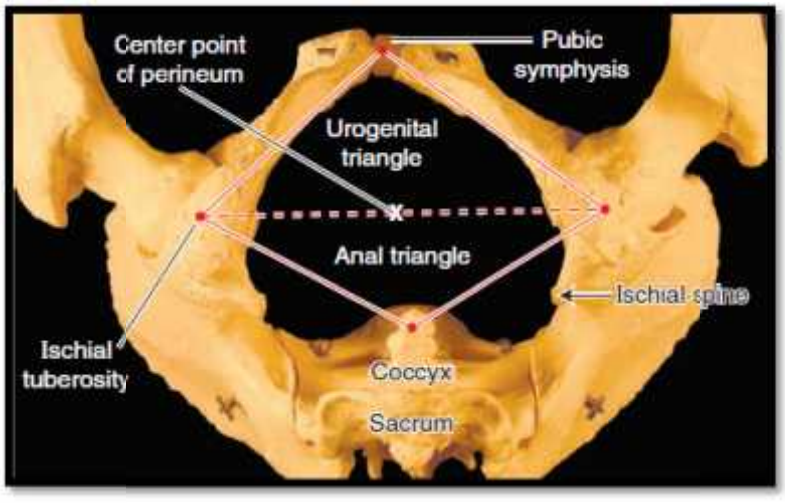


Fig 2. Triangles of Perineum.

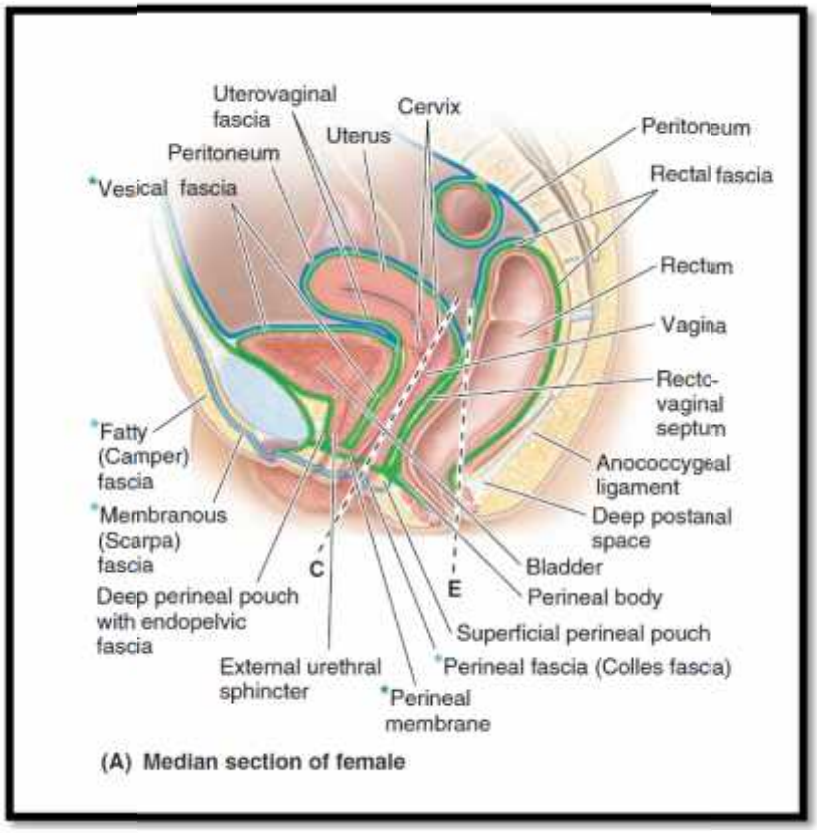


Fig 3. Fasciae of female Perineum.

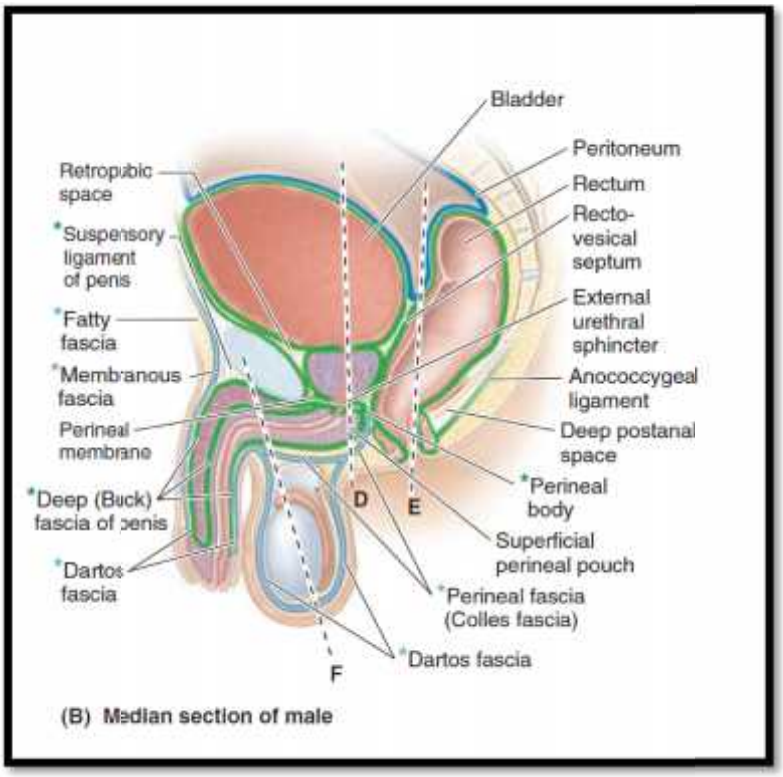


Fig 4. Fasciae of male Perineum.

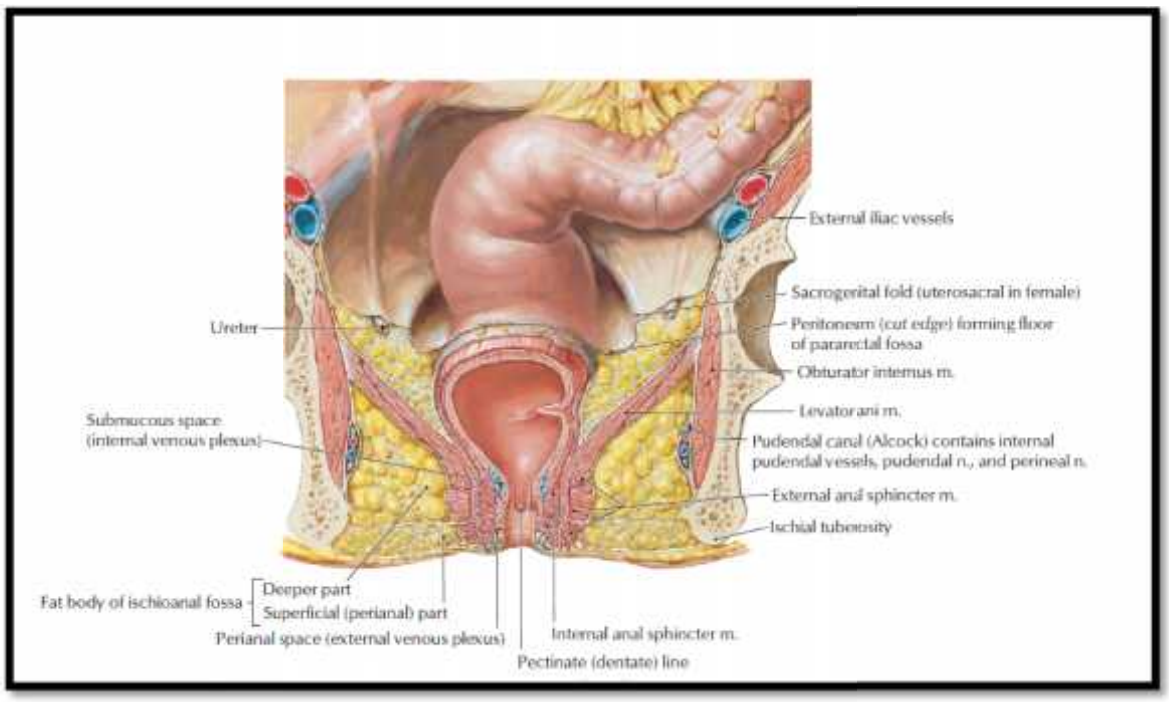


Fig 5. Ischioanal Fossae

ANORECTAL DISORDERS

Anorectal diseases are the group of disorders that arise at the juncture of rectum and anal canal. The commonly described benign anorectal disorders include Haemorrhoids, Anorectal Abscess, Fissure-in-Ano, and Fistula-in-Ano.

Fissure in Ano

An anal fissure depicts an ulcer which is linear and in the midline, and which is distal to the dentate line. These can be easily appreciated by the gentle stretching of the gluteal folds. Most of the fissures are appreciated in the posterior midline. Anterior midline fissures are more commonly seen than lateral fissures. Other findings consist of a hypertrophied anal papilla proximal to the fissure and a sentinel tag at the distal portion of the fissure. Fissures which occur laterally should raise the suspicion of other associated diseases, such as tuberculosis, syphilis, Crohn's disease,

HIV/AIDS, or carcinoma. Anal fissure most often presents withagonizing anal pain (because of it extending onto the highly sensitive anoderm) with defecation and bleeding with defecation.

Patients typically present with a prior episode of constipation. Digital rectal and anoscopic examination mostly results in severe excruciating pain and is not necessary if the visualization of the fissure is possible. A fissure demands an examination under anesthesia, along with a biopsy of the fissure if required, or an endoscopic examination if the fissure is unmanageable with medical therapy. [6]

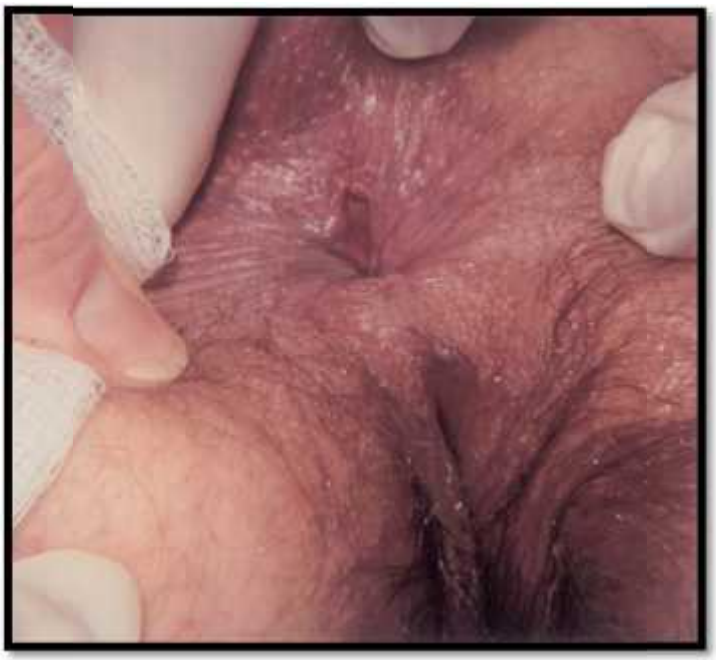


Fig 6. Posterior midline anal fissure

The management of the fissure consists of either

1. Subcutaneous Lateral Internal Sphincterotomy or
2. Advancement Flaps.

Subcutaneous Lateral Internal Sphincterotomy (Fissurectomy):

This is the most commonly done procedure where the internal anal sphincter is partially divided. The radius of the fissure is a good marker for determining the breadth of the sphincter to be released. Excessive release of the sphincter may complicate the situation leading to passive incontinence later on whereas a deficient release will cause treatment failure.

Advancement Flaps:

This management is done in the case of patients with preexisting incontinence along with external sphincter damage by Low forceps delivery, or, the presence of a fissure alongside a low resting anal pressure. A Sphincterotomy alone is not expected to heal these.Here the preservation of the internal sphincter is done along with the excision of the fissure and any sentinel pile. To transfer a healthy, well vascularized tissue into the bed of the fissure, a diamond fashioned anal advancement flap is put.[7]

Perianal Abscess

Perianal cryptoglandular infection is the most common cause of anorectal pus discharge is. Other causes of the perianal infection include hidradenitissuppurativa and Crohn's disease. The perianal abscess is the acute manifestation of the infection which may lead to a fistula in chronic cases.

Perianal/anorectal abscesses most of the times occur at the intersphincteric space. It is possible that the infectious process remains isolated within the intersphincteric space. It can also extend to the surrounding region in an upward, downward, horizontal, or circumferential direction. Classification of these abscesses

is done on the basis of location and are usually described as Intersphincteric, perianal, ischiorectal and supralevator abscesses. [6]

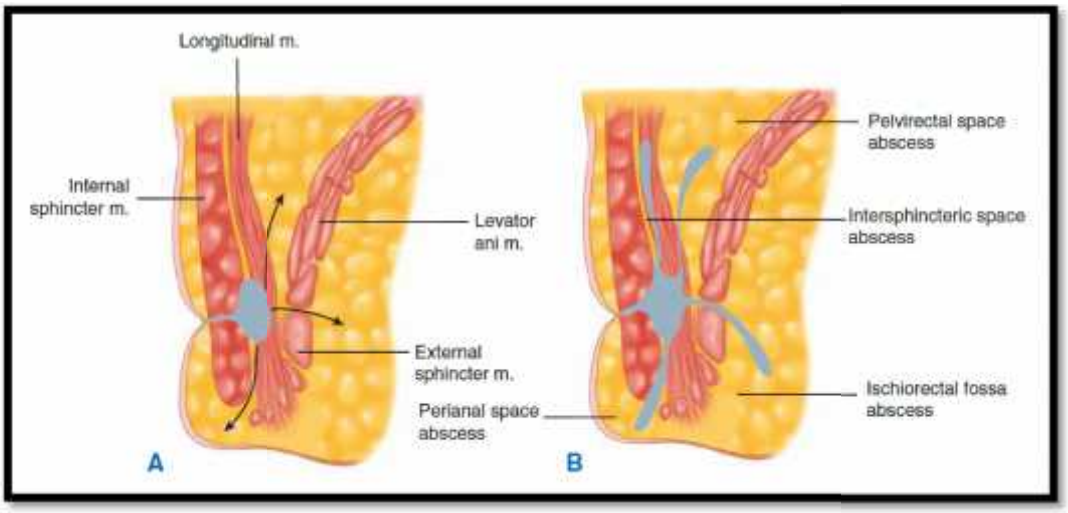


Fig 7.A and B. Pathways of anorectal infection in perianal spaces. m = muscle

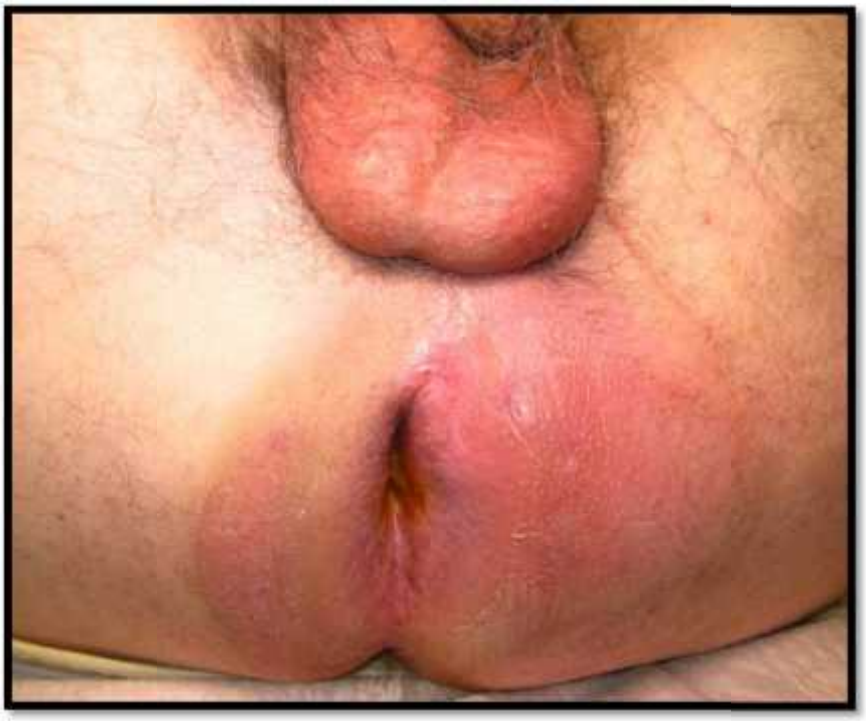


Fig 8. Perianal abscess

The management of the perianal abscess is done by the procedure of incision and drainage. A cruciate incision is made over the swelling and then de-roofing of the cavity with either an elliptical incision or by excision of the flaps in order to provide a good drainage to the wound. [7]

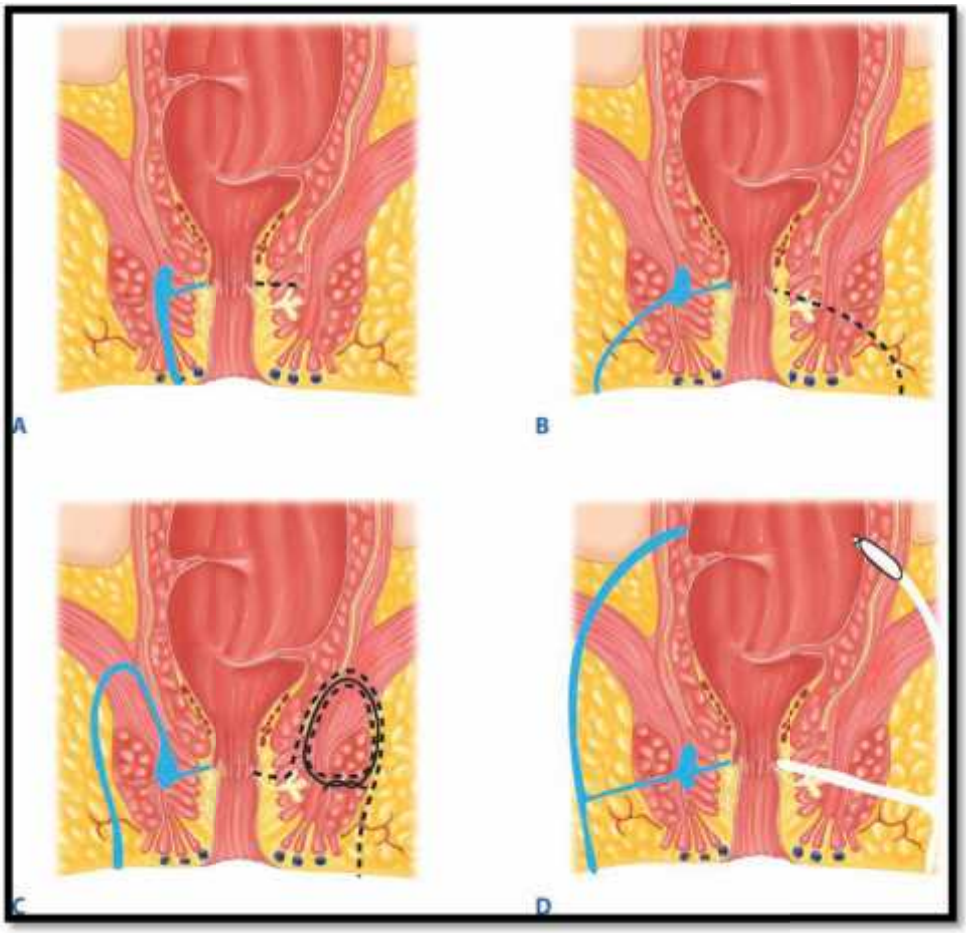
Fistula in Ano

Fistula in ano could be experienced in the acute stage of sepsis in 40% of the patients. Intersphincteric type is the most commonly seen type of fistula. The fistulous tract traverses downwards towards the anal margins in most of the cases. However, in some cases, this fistulous tract may traverse upwards into the rectal wall which may or may not have a perianal ostium.

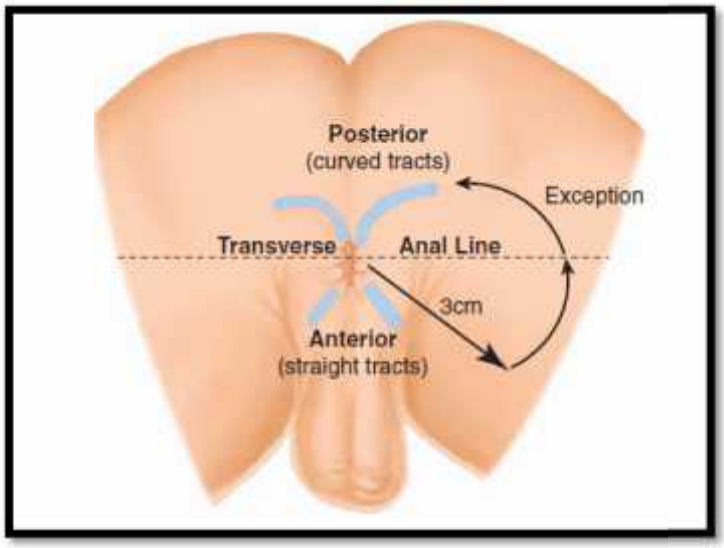
In case of a trans-sphincteric fistula, the track traverses the external sphincter crossing the ischiorectal fossa and ending into the perineal skin. The treatment is easier if it traverses the muscles at a lower level; however, the repair gets complicated if the upper portion of the sphincter is involved. Probing of these fistulas must be done carefully to prevent the unintended perforation of the lower rectum, leading to the formation of an extrasphincteric iatrogenic fistula.

Suprasphincteric fistulas are amongst the rarely experienced fistulas and tend to be challenging at management. The route of these fistulas is superior to the muscles of continence. Moreover, an extension is often observed in these fistulas which runs parallel to the rectum.

Extrasphincteric fistula is also a rare type of fistula which is oft-times seen in iatrogenic injuries. It course of extends from the levator ani till the perianal skin. The fistulous tract lies completely outside the sphincter complex. A colostomy is often required in these fistulas. [6]



A – Intersphincteric Fistula with low tract. B – Trans-sphincteric uncomplicated fistula. C – Suprasphincteric uncomplicated fistula. D – Extrasphincteric fistula



Goodsall's rule for determining the internal opening of fistula.

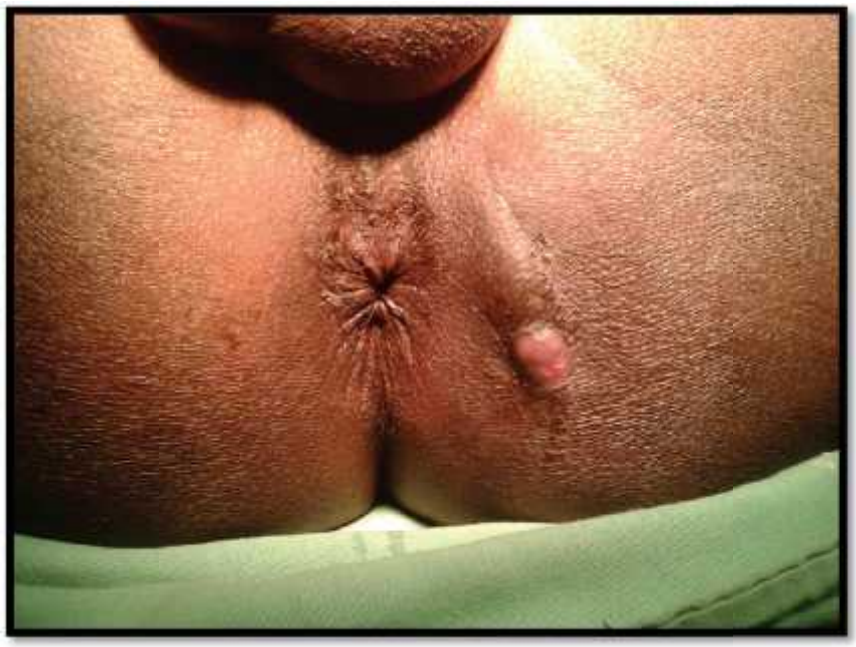


Fig 9. Fistula in ANO

The various methods for the management of fistula include:

1. Fistulectomy and Laying open of the tract
2. Seton Wiring
3. Advancement Flaps

Fistulectomy and Laying open of the tract

A technique based on the concept of excision of part, or the whole length, of the mature fistula tract, removing just the core of sphincter muscles through which it passes. This is although commonly performed, a difficult operation, and the approach can be either from outside the sphincters or via the intersphincteric plane. Success is probably dependent on obliteration of the internal opening and eradication of residual intersphincteric sepsis, rather than complete excision of the track.

Seton wiring

A seton is a thread that is introduced along the track of a fistula and left *in situ*.

Loose seton:

A loose seton ensures continuous drainage of any discharge and prevents premature closure of the external opening, which is the forerunner of recurrent sepsis. It is frequently a temporary measure to render a track more suitable for definitive treatment.

Cutting seton:

A cutting seton is a definitive treatment of a fistula. A cutting seton works by slow division of the sphincters that it encircles, and the fistulous track becomes progressively 'lower' until finally the seton falls out. The advantage of the slow division of the sphincter is that only a small length of sphincter is divided at any one time and the portion sectioned is prevented from retraction by the intact sphincter above and below. In addition, there is inflammatory tethering of the cut ends of the sphincter muscle. Healing occurs sequentially from above downwards with a narrow fibrous scar, which in turn prevents retraction of the fibres of the next portion that is divided.

Post-operative management:

Post-operative wounds of the fissure, fistula and perianal abscess are managed with light dressings and sitz bath two to four times a day besides maintaining local hygiene around the wound site.

The surgical wounds are allowed to heal with time and allowed for spontaneous epithelization in uncomplicated cases. Occasionally, some cases may require a secondary suturing on a later date.

Historical Perspective

Perianal surgeries such as Fissure/ Fistula/ Abscess surgeries have been performed since the ancient times and the wound management methods have kept on evolving through the times.

Earlier, the surgeons used to do suturing for the post-op wounds in these cases but it was later discovered that leaving it open was a better option as there used to be recurrent infections in the sutured wounds due to the close proximity to the anal region which is a zone of maximum pathogen concentration over the surface of the body.

Regular antiseptic dressings and leaving the wound open was admitted as a conventional procedure for the management of these wounds.

Later, Sitz-bath was discovered as an efficient way of relieving the severe pain experienced by this set of patients. Additives like salt, sodium bicarbonate and iodine were later put into use as additives to promote healing and provide analgesia.

The Sitz bath is a relatively safe procedure. However, potential complications have been reported, such as infection, due to sharing of tub between patients, and perineal burn.

Fig 10. Sitz Bath Bucket used in old times.

Fig 11.Sitz Bath Tub.

Sitz-Bath in Clinical Practice

Sitz-Bath is time and again recommended by the physicians for a variety of perianal surgeries in their post-operative period. The name 'Sitz' has its origin with the German word 'Sitzen', meaning 'To sit'. Pain that is related to post-operative perianal surgical wounds could be relieved with the use of Sitz-bath, a relatively easy procedure that involves filling of a bathtub/flat-bucket with warm water.

An additive, such as salt/sodium bicarbonate or povidone iodine may be used. As per the recommendation, a sitz bath is customarily carried out two to four times per day in addition to once after every defecation. The patient has to submerge the perineal region and pelvis in a tub filled with warm water, with or without the addition of extra compounds.

Fig 12.A patient taking sitz-bath.

Shafik et al. reported that the Sitz-Bath is efficacious in relieving pain due to the thermosphincteric action.[8]

Wultzer et al. demonstrated that the healing occurs due to the antiseptic properties of povidone iodine which is used as an additive to the Sitz-bath.[9]

Besides anorectal disorders, the Sitz bath is used widely to relieve perineal pain for post-partum women.[10]

Lafoy et al. reported that a cold Sitz bath was more efficacious in relieving the perianal pain as well as the post episiotomy edema, compared to the warm Sitz bath.[11]

Tejirian et al. described the mechanism of a cold sitz bath where vasoconstriction, local anaesthetic effect and the resolution of muscle irritability and spasm occured.[12]

However, in the scenario of the anorectal disorders under focus, a warm sitz bath is preferred over the cold bath.[13-15]

The working of a warm sitz bath in relieving the anorectal pain has been obscure. According to the hypothesis of Shafik et al. the warm sitz bath acts by activating the neural pathways leading to relaxation of internal anal sphincter, leading to the attenuation of the rectal neck pressure and the electromyographic activity of the internal sphincter via the Thermosphincteric Reflex.[1]

There are certain problems faced with Sitz-bath in the Indian population setting considering the low socioeconomic condition of the larger proportion of our population. Sitz-bath requires:

1. Privacy.
2. Need for a Sitz-Bath Tub or a Flat Bucket.
3. Multiple Sittings every day.

These factors decrease the Sitz-bath usage in the majority of low socioeconomic population due to the inconvenience, and lack of time, which may ultimately lead to non-compliance and improper wound healing.

Silver in Clinical Practice

Silver has been used as an antibacterial agent since a long time in sulfadiazine paste and colloidal dispersion gel forms due to its property of oxidation and release of silver ions which causes destruction of the bacterial wall. Microbes are unable to develop resistance to silver due to its action being divergent as compared to the conventional antibiotics. Recently, nanoparticle sol formulations in the form of silver spray have been devised and are available to the patient. Nanoparticle formulations have the benefits of colossal surface area, a fierce reactivity and easy penetrability due to the extremely small size of particles.[3]

In spray form, the silver colloidal solution, apart from its antiseptic property, also acts as a washing agent which is less time consuming and would be more convenient to the patient as it would not require the tedious procedure of taking a sitz-bath as the patients could spray the wound as per their convenience.

Later, silver containing ointments were put into use for the management of post-operative perineal wounds which proved to be quite efficacious at inhibiting the bacterial growth.

Recently, spray formulations of colloidal silver have come into production and they have certain benefits over the ointment formulation as the application is much easier and the patient can self-administer it at home without the need of a dressing to be done by a skilled professional. Also the patients experience lesser pain with the

spray formulation as compared to the silver ointment as the latter is manually applied to the raw surface of perineal wounds with the use of instruments.

A study was conducted in Tanta Fever Hospital, the patients suffering from infected post-surgical perineal wounds. Recognition and isolation of various organisms was done using the microbiological standards.

44.3% of the isolated microbes consisted of staphylococcus species (S. aureus being 21.3% and rest of the 23% constituting the coagulase negative staphylococci). Using the Epsilometer test, it was established that 87% of the S. aureus were MRSA whereas the rest were MSSA. Amongst the S. epidermidis species, 95.2% were MRSE and only 4.8% were MSSE.

*S.aureus*is responsible for the superficial as well as the deep seated infections in the body encompassing the hospital as well as the community acquired ones.[16] *S.epidermidis*has been notoriously associated with antibiotic resistance leading to a multitude of infections.[17]

Hence, it is said that the aureus and epidermidis species are the root cause of the devastating strain on the healthcare system.[18,19] In most cases, the contagion arises from the immediate contact with the wounds, urinary catheters, and tubing such as the feeding or respiratory tubes.[20]

In recent times, the application of nanotechnology has been proven to be extremely effective against the resistant organisms. Due to the mechanism of action of the nanoparticles (NP's) being disparate as compared to the conventional antibiotics, the microbes are not able to develop resistance against them.[21]

Due to the extremely small size of particles, the colossal surface area, a fierce reactivity, the nanoparticles have an easy penetrability into the biofilm matrix and cell membranes.[22]

The silver nanoparticles are materializing as the most rapidly expanding category of biomedical products.[23] They have a very broad spectrum activity towards gram positive/negative as well as even the fungal pathogens, also they have a very good capability of coping with the resistant strains as they act synergistically by varied mechanisms and multiple targets leading to failure of the generation of a resistance mechanism.[3]

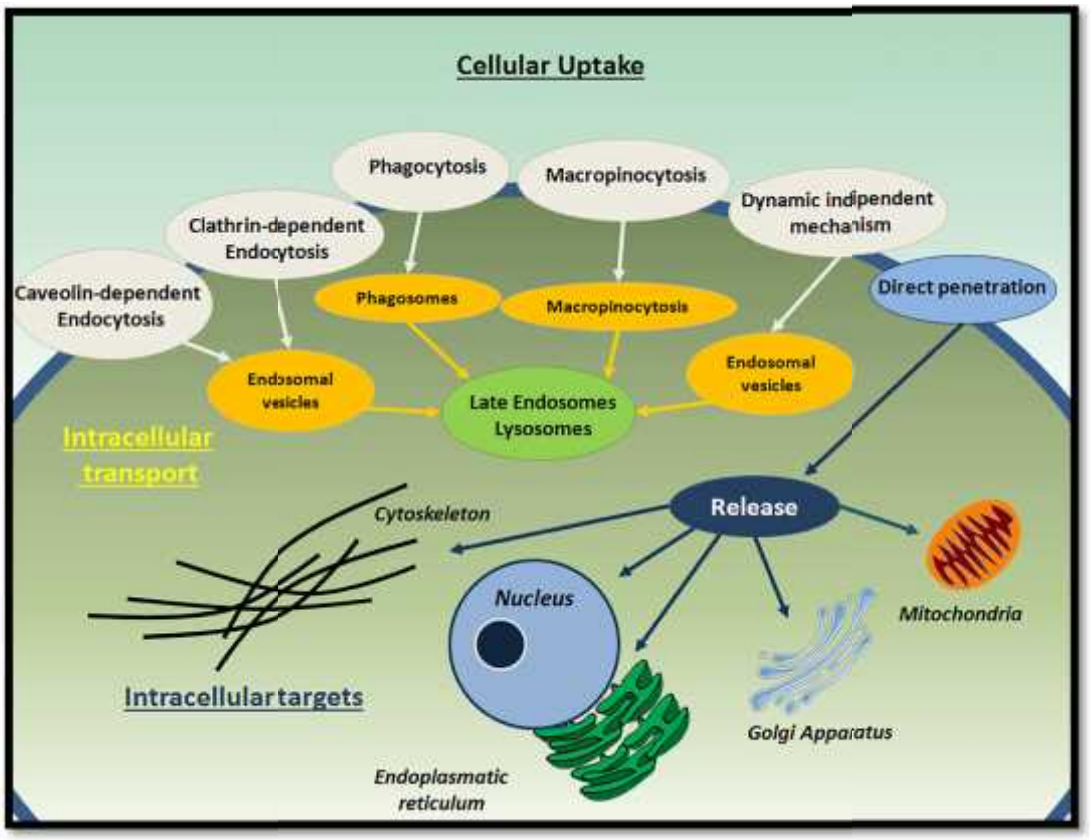


Fig 13. Intracellular mechanism and targeting of AgNP's.

Interaction of Silver Inside The Human Body

Silver "is highly efficacious towards bad bacteria but it doesn't hamper the good ones (intestinal bio-flora)", and "it acts as a secondary immune system". It is a transition element which pertains to the noble group of elements.[24-26]like many other elements, [27-30]it has nil biological reaction and is toxic, specifically towards lower organisms. Silver is present in trace amounts in the food that we consume on a daily basis: flour comprises up to 0.3 ppm, bran has 1 ppm, fish has 10 ppm, milk 50 ppb, meat 40 ppb.[31-33] It can be forenamed that the silver in food lies in the 10−100 μg/kg range, although in the natural sources of water, it is 0.2− 0.3 μg/L.[34]

Daily intake of silver in humans can be in the range of 20−80 μg in accordance with the type of diet,[35,36] but the bodily absorption of the metal is only 10%, 90% is excreted out of the body via shedding of intestinal epithelial cells which contain silver.

The study evidenced that the whole body retention in monkeys, rats, and mice was rather low, less than 1% of the initial dose after 1 week, while in dogs the amount was higher although lower than 10% of the initial dose.[37]

The reticuloendothelial organs are the primary cells which retain silver inside our body. Upon intravenous administration of silver, it was found in spleen, liver, bone marrow, lungs, muscle, and skin tissues, with its levels decreasing in the same order.[38]

History of Silver in Medicine

It was a common practice in the ancient civilizations, such as Greeks and Romans to use silver vessels for storage of water so as to keep it consumable for very long periods of time. The generalized knowledge that such an application could prevent festering and degradation probably led to the tradition of the use of silver by

the wealthy throughout the history. In the early 1800s, doctors used to suture operated wounds with silver wires, and silver leaves were applied over the wounds of soldiers during world war in order to impede infections and accelerate the process of wound healing.

There has been a luxurious use of the silver preparations in the medical scenario at the beginning of 20^{th} century, for example, as a germicidal solution in hospitals. Esteemed medical journals have characterized the effectiveness of silver colloidal formulations as bactericides with nil detrimental drawbacks.

In 1918 a paper by T. H. Anderson-Wells demonstrated that a preparation of colloidal silver was used intravenously, with no discoloration of the skin as well as without any adverse effects to the kidneys.[39]Lately, the silver and its amalgamations have reobtained their popularity as n substitute drug for a battery of diseases and pathologies.

In the past, silver and its compounds have been inducted into the management of not only the pathologies such as syphilis, gastroenteritis, conjunctivitis, and gonorrhea but also to treat nicotine dependence and mental ailments.

For decades the solution of silver nitrate (2%) has been the sole treatment for conjunctivitis in neonates (i.e. ophthalmianeonatorum), after the introduction by Dr. Crede in 1881. In a formulation of 0.5% solution, nitrate of silver has also been applied to the patients of burns[40] or in the eradication of the cutaneous warts which has been a distinctly triumphant method.[41]

Proteinates of silver had a prominent role in the clinical practice in the earlier days. Nowadays employed as 8% silver compound, Protargol, bound to albumin, has been used for positive staining of carbohydrates during electron microscopy besides being used for staining nervous tissue with light microscopy. Moreover and

interestingly so, its widespread application in the medical history for the management of gonorrhea was observed before the era of antibiotics. Arthur Eichengrün was a German scientist who pioneered the use of silver proteinate formulation as a remedial option in 1897.[42]

name	definition	use	% of Ag
Albargin	Gelatose silver or silver glutin	Bowel wash and treatment of gonorrhea	15
Argentamin	Silver phosphate in ethylenediamine solution	Antiseptic astringent and disinfectant	10
Argonin L	A compound of silver nitrate and casein-soda	Treatment of gonorrheal opathalmia and purulent ophthalmia	10
Argyrol	A compound of silver with a wheat protein	Wide range of indications especially in ophthalmic practice	30
Collargol	Colloidal silver used as a solution and in an ointment	Ophthalmic indications	
Ichthargan	Silver ichthyolate	Infections of the genitourinary tract	30
Largin	Silver albuminate	Treatment of gonorrhea	11
Protargol	Silver protein	Treatment of chronic inflammation of the conjunctiva	8

Table1. Some Silver Compounds used in the historical times.

Silver in Medicine Today

Many formulations of silver based medications have been used over the centuries in the past and now a subset of the more efficacious ones are being developed into superior compounds for innovative and unique applications. For example, fluorides of silver are inducted in the management of hypersensitivity of teeth as well as the dental caries, management;[43] Nitrates of silver are being used for the management of abscesses and cysts[44-46] as potent antifungals against the two species of pathogenic fungi viz. Aspergillusflavus and Penicillium vulpinum[47] as well as the fungi affecting the eye viz. Fusarium species and Aspergillum species.[48]

Silver alginate, a newer compound, has been proven to be highly efficacious in preventing the central line derived infections in case of VLBW (very low birth weight) neonates.[49]

With technological advancements, peculiar silver compounds have emerged as propitious drugs for the forthcoming treatment scenario. Nowadays, AgNP's are taking up the lion's share in the medical field when it comes to the application of silver. The mechanism of cytotoxicity is accredited to the potential damage done to the pathogenic bacterial as well as the cancer cells by the silver ions[50,51]

Mechanisms of action of Silver Ions

Debilitation of Ion Exchange: Silver cations (Ag+) cause accumulation of phosphate by inhibition of phosphate exchange and uptake, in turn leading to release of K^+ ions, ultimately disposing of the motive proton force across the plasma membrane of the cell.

DNA and RNA Cross-linking: Silver ions discombobulate the process of cell cycle progression in an efficient manner due to their ability to bind to 'nucleic acids'.

Denaturation of cellular proteins and Inactivation of enzymes: Silver ions form complexes with the donor groups of proteins and peptides by actively and strongly interacting with the latter, more so with the phosphate and thiol moieties amongst the others. Such a binding results in the change of the protein structure and subsequent deactivation of the enzymatic properties of crucial enzymes such as lipoxigenase[52,53]and thioredoxin reductase.[54] Also, reduced glutathione has a very strong interaction with Ag+. Moreover, it disrupts the formation of iron-sulfur cluster.[55]

Shriveling and Disintegration of Mitochondrial and Plasma Membranes: The silver ions can induce a monumental leakage of the plasma membrane of bacterial cell through binding of the ions to the polar membrane i.e bilayer of phospholipids.[56] These also cause removal of one negatively charged electron from the plasma

membrane leading to disruption of its permeability and integrity.[57] Moreover, Ag+ cause mitochondrial membrane depolarization and disruption of homoeostasis.[58-60]

Transformation into Non-Culturable Viable Bacteria (VNBC's): Silver ions transform pathogenic cells into a weak state of metabolic stagnation and division inertia. Devoid of anabolic activity, the pathogenic cells get smaller and smaller in size ultimately ending in the death after a certain period of dormancy.[61]

The "Zombie" effect: The microbes that are killed by the Ag+ ions cause induction of lysis in the adjoining bacteria. The dead cells serve as a cistern of lethal Ag+ ions which get disseminated and siphoned into the abutting cells, subsequently relaying the noxious action.[62]

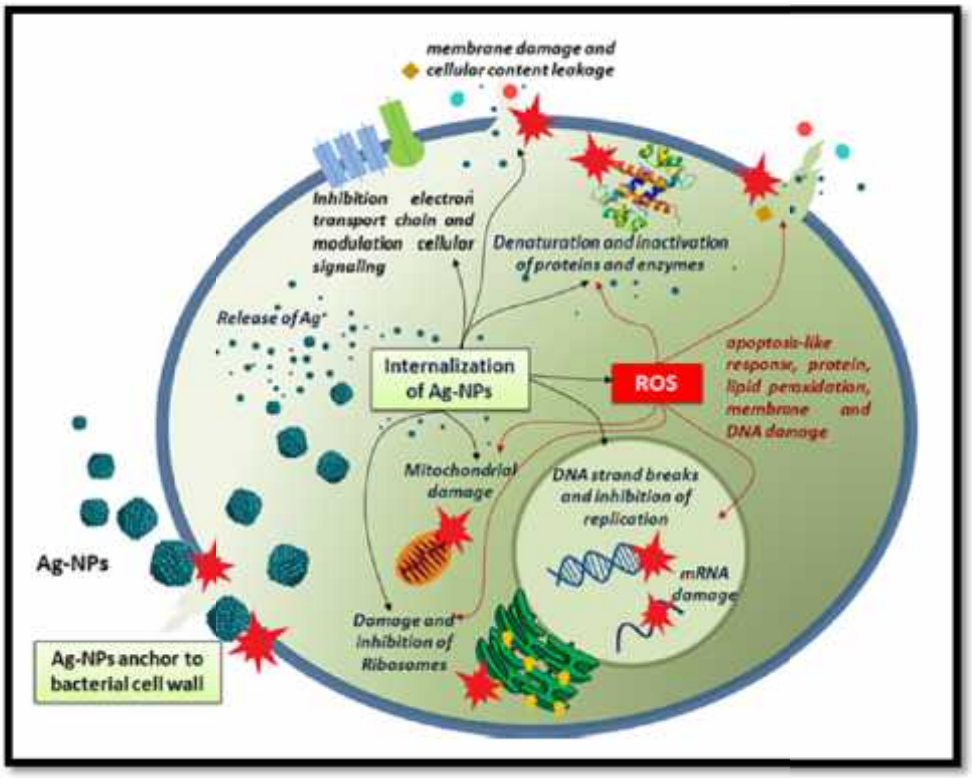


Fig 14. Antimicrobial routes of action of AgNP's

Theranostics

"Theranostics is a newly coined word which defines the combined application of Nanotechnology and Medical Therapy".

The most prized utilization of the AgNP's has been against the pathogenic microbes. Consolidating the facts, it is remarkably significant that these ionic forms have expressed superior lethality towards the diverse gamut of gram +ve as well as gram –ve bacteria encompassing, especially, even the Multidrug-resistant forms.[63] Moreover, these particles have a profound action against biofilms, which many traditional antibiotics fail to act upon.[64]

MATERIALS AND METHODS

At a tertiary care center, Dr. Prabhakar Kore Hospital, over a period of one year (Jan 2019 to Dec 2019), 79 patients were enrolled for the study, out of which 5 patients declined to participate in the study and 3 patients were excluded due to diabetic comorbidity. 71 patients were randomized and allocated into 2 groups: 36 (test) and 35 (control) patients. 3 patients were lost to follow up. So, a total of 68 patients were finally analysed who were operated for perianal conditions viz. fissure in ano, fistula in ano, and perianal abscess and were divided into 2 groups of 34 each receiving iodine sitz bath and colloidal silver spray, respectively. The outcomes were measured using scales i.e. **Visual Analogue Scale** (VAS), **Likert Scale, Wound Healing Score**and **Compliance score**.

INCLUSION CRITERIA:

- Patients who are aged >18 years
- Patients who have been diagnosed with an anorectal disorder viz. Fistula in Ano, Fissure in Ano& Perianal Abscess and have undergone a surgical procedure for the same.

EXCLUSION CRITERIA:

- Patients with fissures coexisting with systemic diseases (diabetes, human immunodeficiency virus infection, and other immune-compromised states)
- Patients with complicated fissures (Fissures at atypical locations associated with Tuberculosis or Crohn’s disease)
- Patients with Atypical Fissures associated with Inflammatory Bowel Disease or Cancer or Anal Infection.
- Pregnant and lactating women.

Data Collection

Sample size:

Using the formula:

$$n = \frac{2(Z\alpha+Z\beta)^2 PQ}{(P1-P2)^2}$$ Assuming, **P1**:55%, **P2:20**%

Where, Zα: 1.96, **Zβ**: 0.84

Sample size was calculated assuming, the time taken for granulation tissue appearance in weeks as primary outcome. Assuming 35% difference in the proportion of ulcers developing granulation tissue by end of 2 weeks as clinically significant, with 80% power and 5% two sided alpha error, 31 people were required in each group. To account for loss to follow up of 10% another 3 subjects were added to each group. Hence the final sample size would be 34 in each group.

Sampling method:

Randomization: The patients who were operated for the said conditions were randomly allocated to both the intervention groups using computer generated random number sequence.

Blinding: Considering the nature of intervention, blinding of investigator or participants is not possible, hence the study will be an open labelled study.

Sampling procedure: Computer generated randomised selection.

The patients were randomised into 2 groups:

Group A

Patients receiving Sitz-bath with Povidone iodine as an additive: 34

Group B

Patients receiving Silver colloidal solution spray: 34

Analysis

- The Wound Healing rate was assessed by following up on the patients after discharge with the amount of epithelial covering of the wound with respect to the initial wound size measured using a **Vernier Caliper** at the end of 1 month with a scoring ranging from 0 to 4, where a score of:

  0: 76-100% bare area

  1: 51-75% bare area

  2: 26-50% bare area

  3: 1-25% bare area

  4: Complete Covering

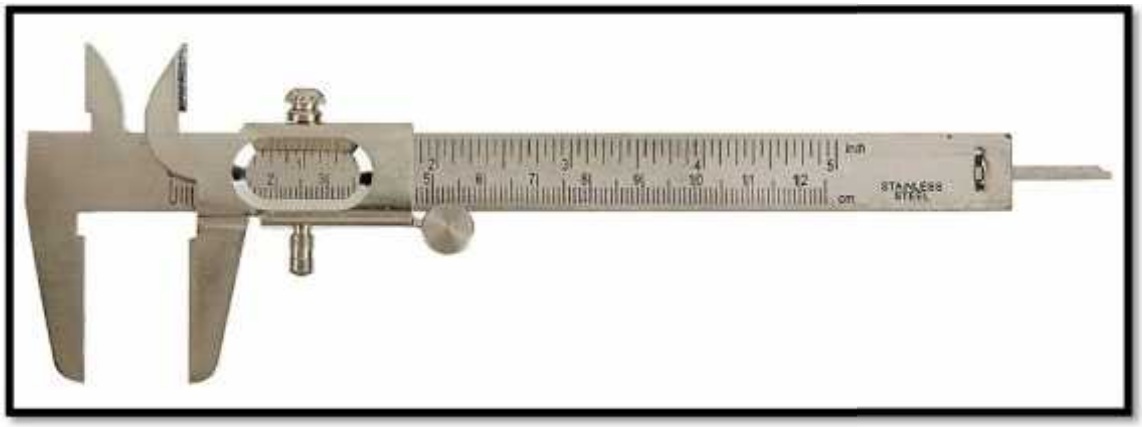


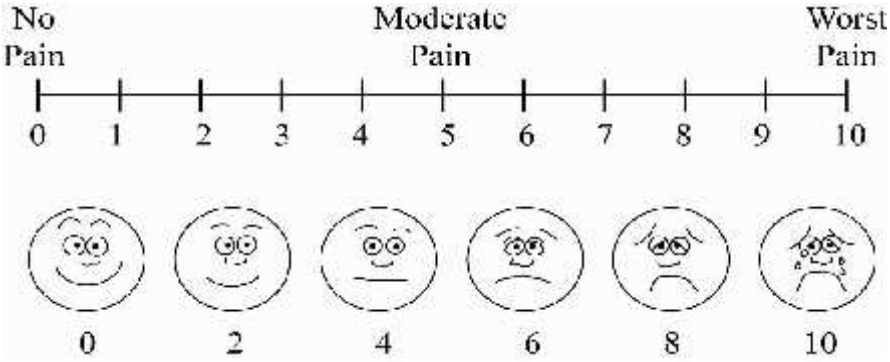
Fig. Vernier Caliper

- The post-operative pain was assessed using **Visual Analogue Scale** (VAS) at
  - 48 hours
  - 72 hours
  - Once every week after 72 hours till complete relief.

- The Convenience level was assessed using the **Likert Scale**with a Range of 1 to 5 with increasing convenience.
- The compliance of the patient towards the procedure was assessed by documenting **how many times in a week**,**the patient has missed the procedureout of 7 days**.
- Scores were calculated for each group and the outcomes will be compared using the Student t-test and Mann-Whitney U test.

1. **AMOUNT OF EPITHELIAL COVERING AT THE END OF 1 MONTH?_____ (SCORE 0-4)**

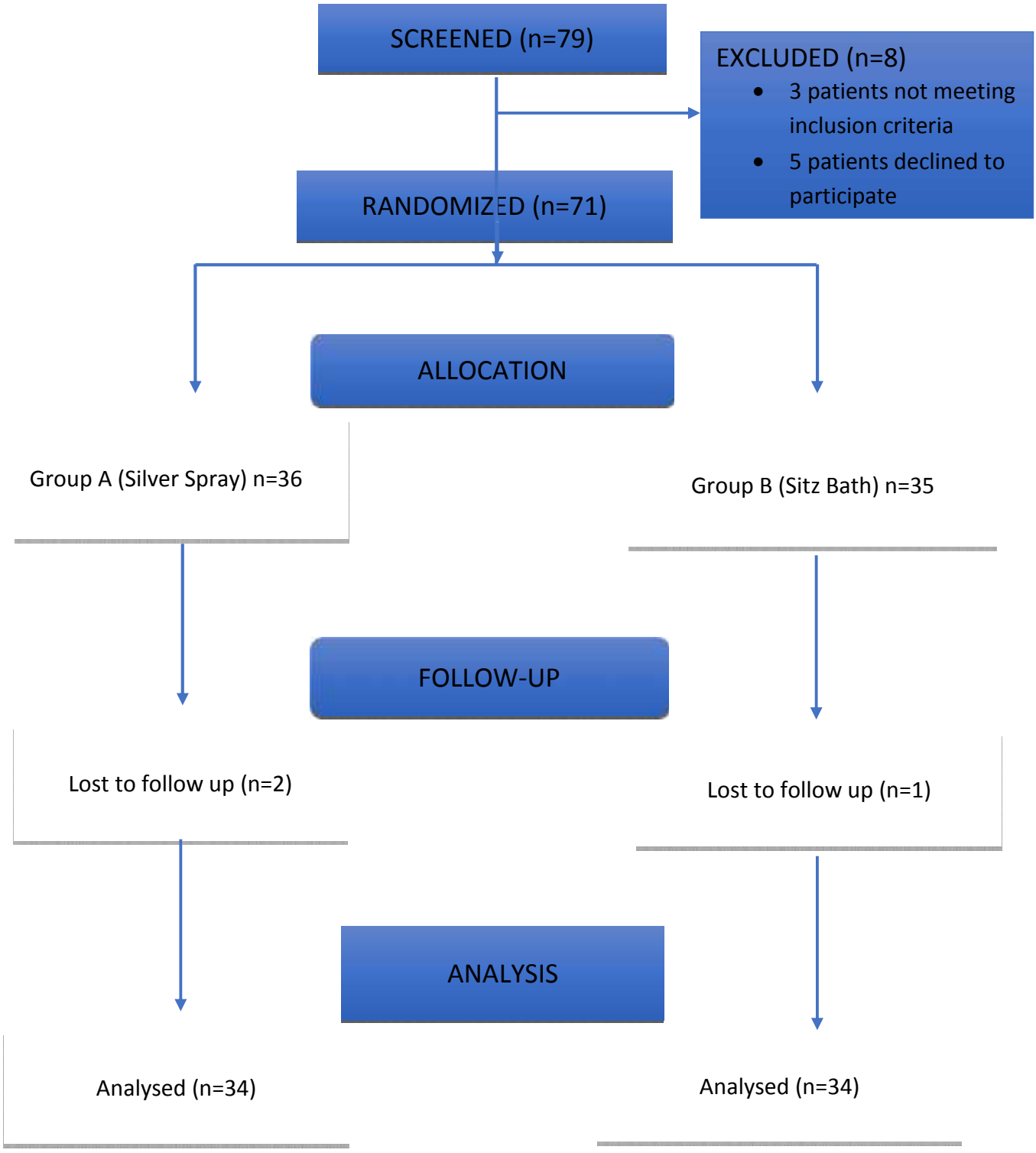
2. **POST OPERATIVE PAIN SCORE ACCORDING TO VISUAL ANALOGUE SCALE:**



1. **CONVENIENCE TO THE PATIENT:**

2. **NUMBER OF TIMES, THE PATIENT MISSED THE PROCEDURE*:*** **_____DAYS OUT OF 7 DAYS.**

ENROLMENT


SCREENED (n=79)
EXCLUDED (n=8)
3 patients not meeting inclusion criteria
5 patients declined to participate
RANDOMIZED (n=71)
ALLOCATION
Group A (Silver Spray) n=36
Group B (Sitz Bath) n=35
FOLLOW-UP
Lost to follow up (n=2)
Lost to follow up (n=1)
ANALYSIS
Analysed (n=34)
Analysed (n=34)

RESULTS

Table 2: Comparison of two groups (test and control) by gender

Sex	Test group	%	Control group	%	Total	%
Male	27	79.41	23	67.65	50	73.53
Female	7	20.59	11	32.35	18	26.47
Total	34	100.00	34	100.00	68	100.00
Chi-square=1.2092 P = 0.2720						

Figure 1: Comparison of two groups (test and control) by gender

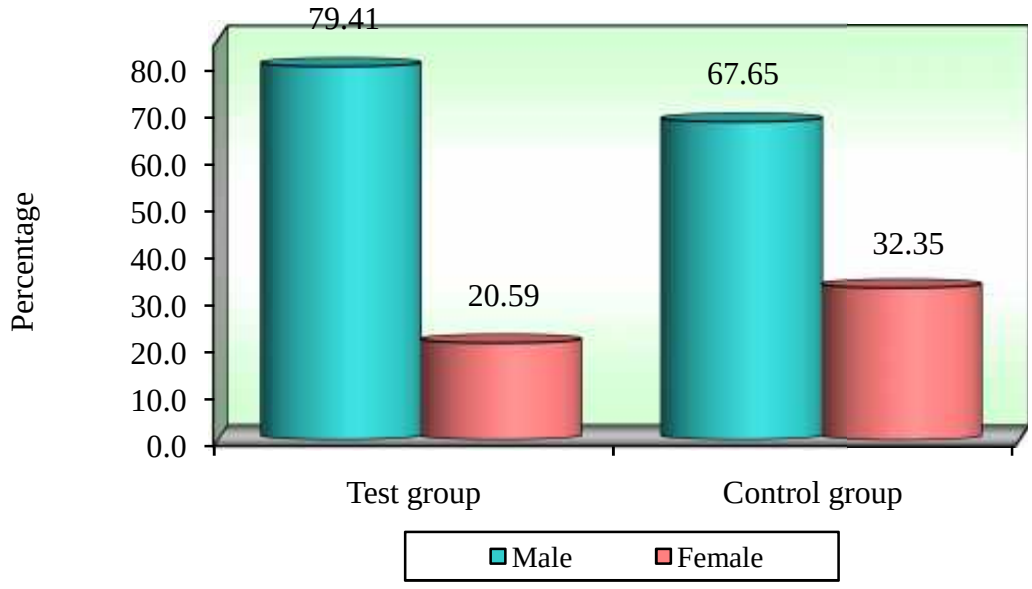


Table 3: Comparison of two groups (test and control) by age groups

Age groups	Test group	%	Control group	%	Total	%
20-29yrs	5	14.71	11	32.35	16	23.53
30-39yrs	7	20.59	8	23.53	15	22.06
40-49yrs	8	23.53	3	8.82	11	16.18
50-59yrs	7	20.59	8	23.53	15	22.06
60+yrs	7	20.59	4	11.76	11	16.18
Total	34	100.00	34	100.00	68	100.00
Chi-square=5.4743 P = 0.2421						

Figure 2: Comparison of two groups (test and control) by age groups

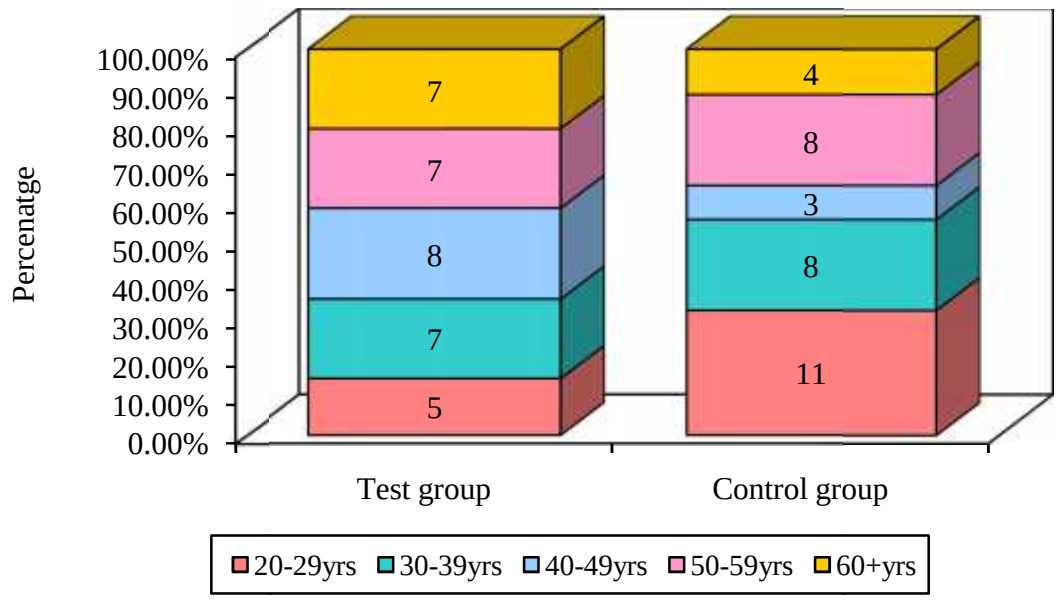


Table 4: Comparison of two groups (test and control) with respect to mean age by independent t-test

Groups	n	Mean	SD	SE	t-value	P-value
Test group	34	45.97	14.71	2.52	1.4940	0.1399
Control group	34	40.68	14.51	2.49		

Figure 3: Comparison of two groups (test and control) with respect to mean age

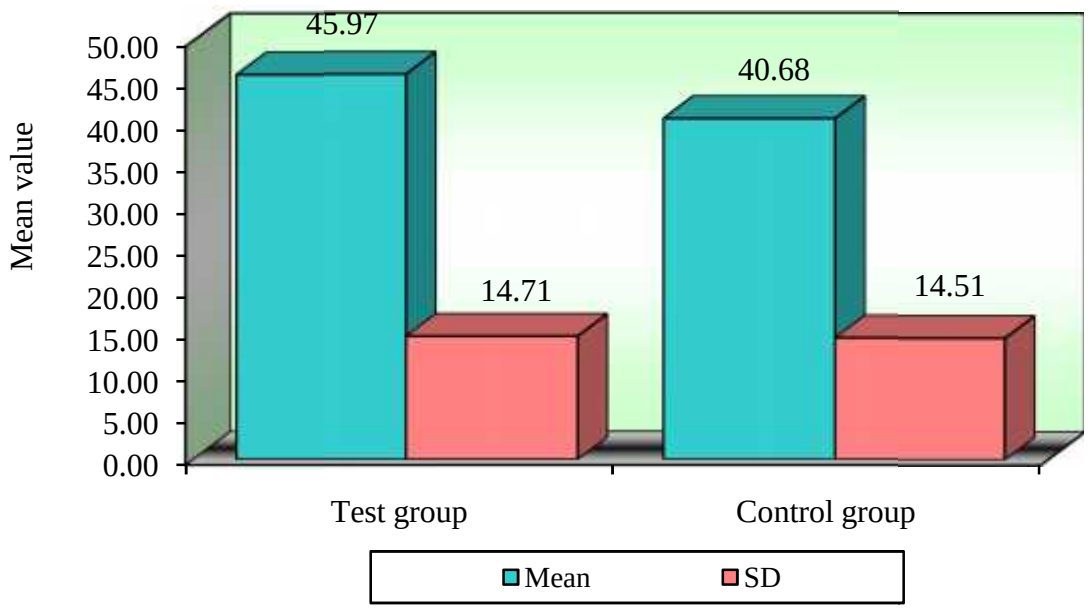


Table 5: Comparison of two groups (test and control) by diagnosis

Diagnosis	Test group	%	Control group	%	Total	%
Fissure in ANO	9	26.47	12	35.29	21	30.88
Fistula in ANO	14	41.18	10	29.41	24	35.29
Fistula & fissure in ANO	1	2.94	0	0.00	1	1.47
Perianal abscess	10	29.41	12	35.29	22	32.35
Total	34	100.00	34	100.00	68	100.00
Chi-square=2.2775 P = 0.5174						

Figure 4: Comparison of two groups (test and control) by diagnosis

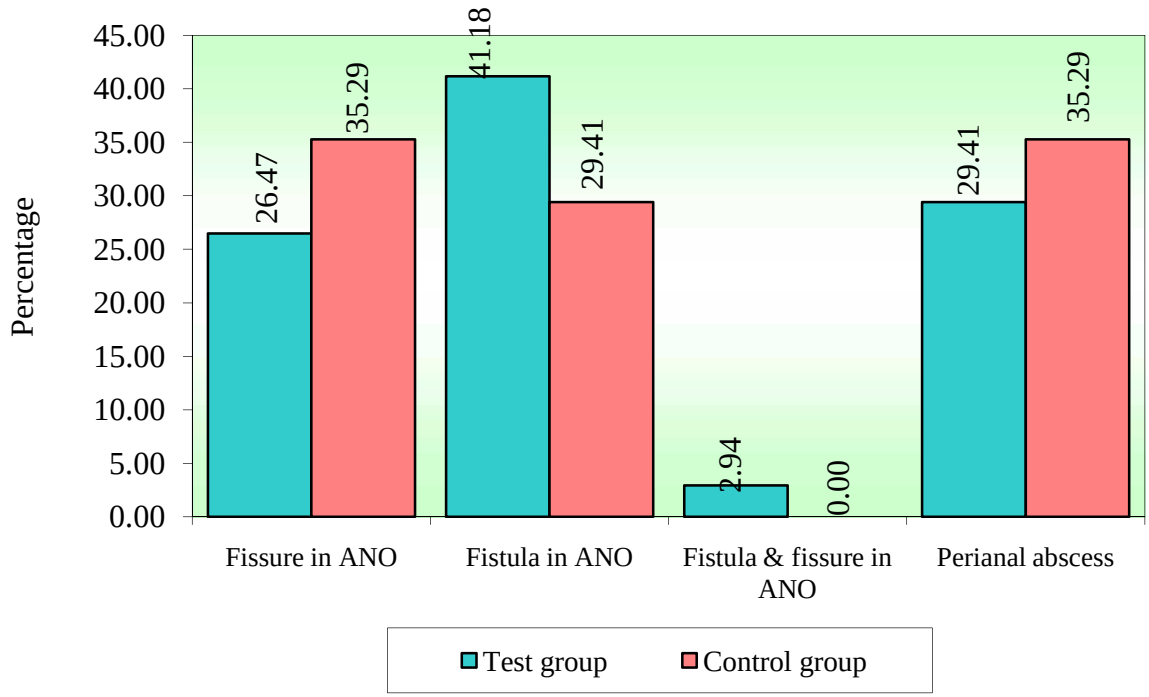


Table 6: Comparison of two groups (test and control) by types of surgery

Types of surgery	Test group	%	Control group	%	Total	%
Fissurectomy	9	26.47	12	35.29	21	30.88
Fistulectomy	14	41.18	10	29.41	24	35.29
Fistulectomy & Fissurectomy	1	2.94	0	0.00	1	1.47
I and D	10	29.41	12	35.29	22	32.35
Total	34	100.00	34	100.00	68	100.00
Chi-square=2.2775 P = 0.5174						

Figure 5: Comparison of two groups (test and control) by types of surgery

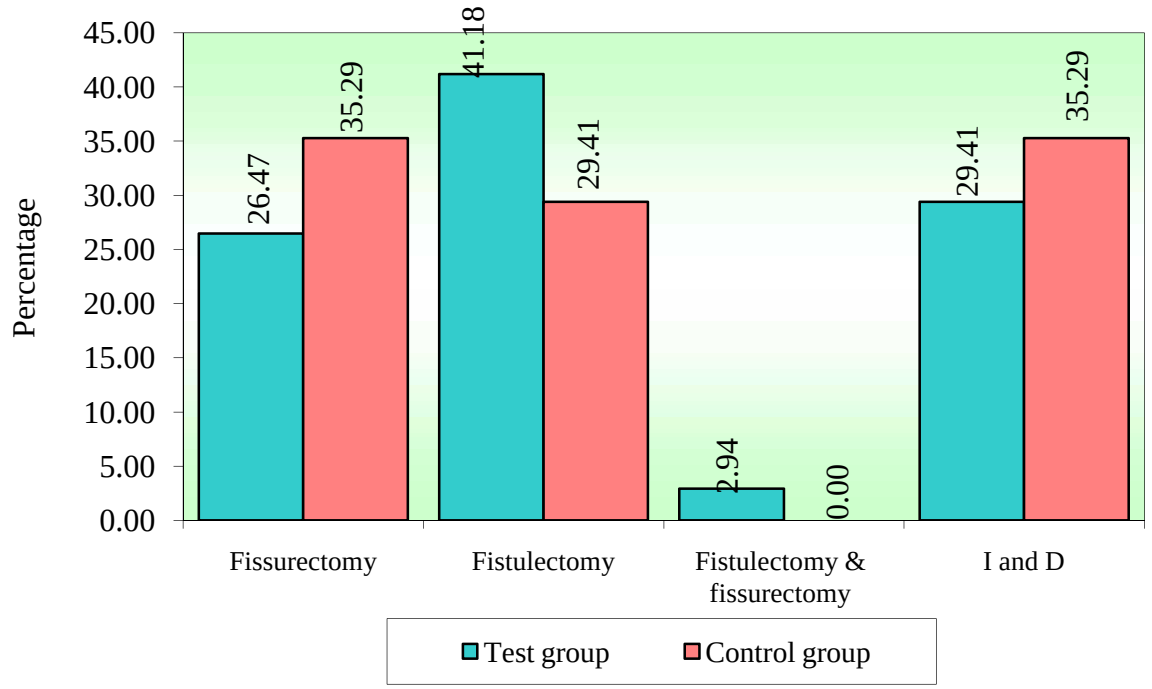


Table 7: Comparison of two groups (test and control) with Epithelial covering scores at the end of 1 month by Mann-Whitney U test.

Summary	Mean	SD	Median	IQR	Mean rank	U-value	Z-value	p-value
Test group	3.65	0.54	4.00	0.50	40.00	391.00	-2.2937	0.0218*
Control group	3.24	0.70	3.00	0.50	29.00			

*p<0.05

Figure 6: Comparison of two groups (test and control) with Epithelial covering scores at the end of 1 month

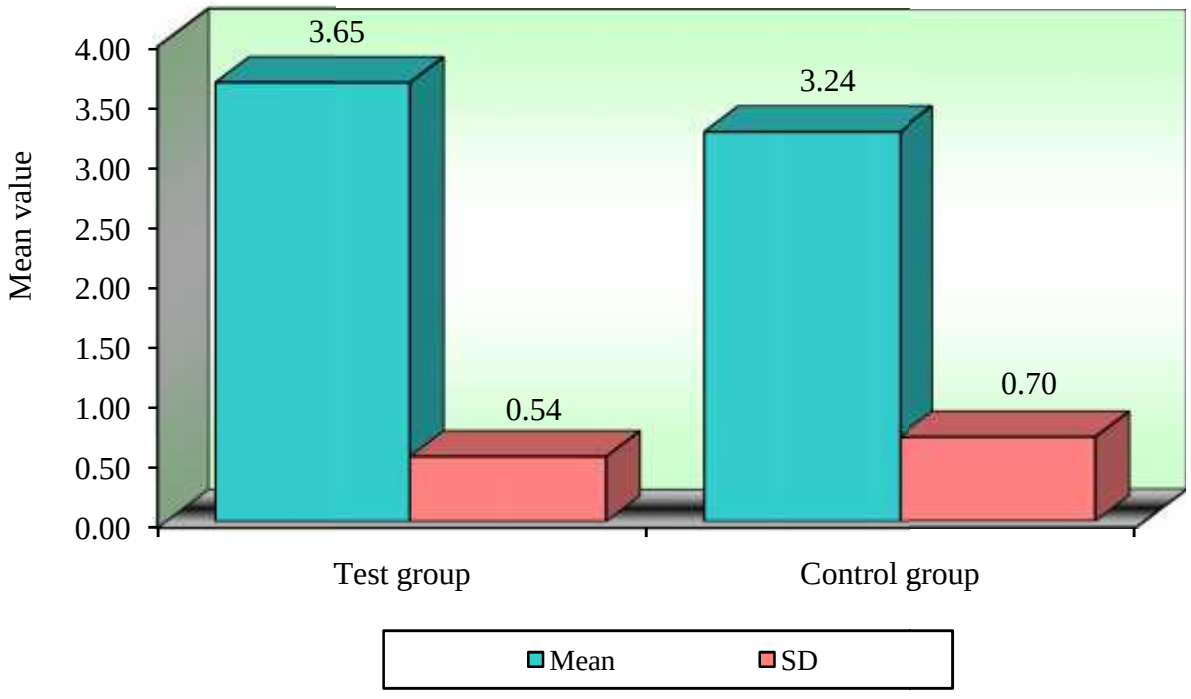


Table 8: Comparison of two groups (test and control) with Post-op VAS Pain scores by Mann-Whitney U test.

Summery	Mean	SD	Median	IQR	Mean rank	U-value	Z-value	p-value
Test group	2.35	2.35	2.00	2.00	28.16	362.50	-2.6432	0.0082*
Control group	3.91	2.45	4.00	1.50	40.84			

*p<0.05

Figure 7: Comparison of two groups (test and control) with Post-op VAS Pain scores

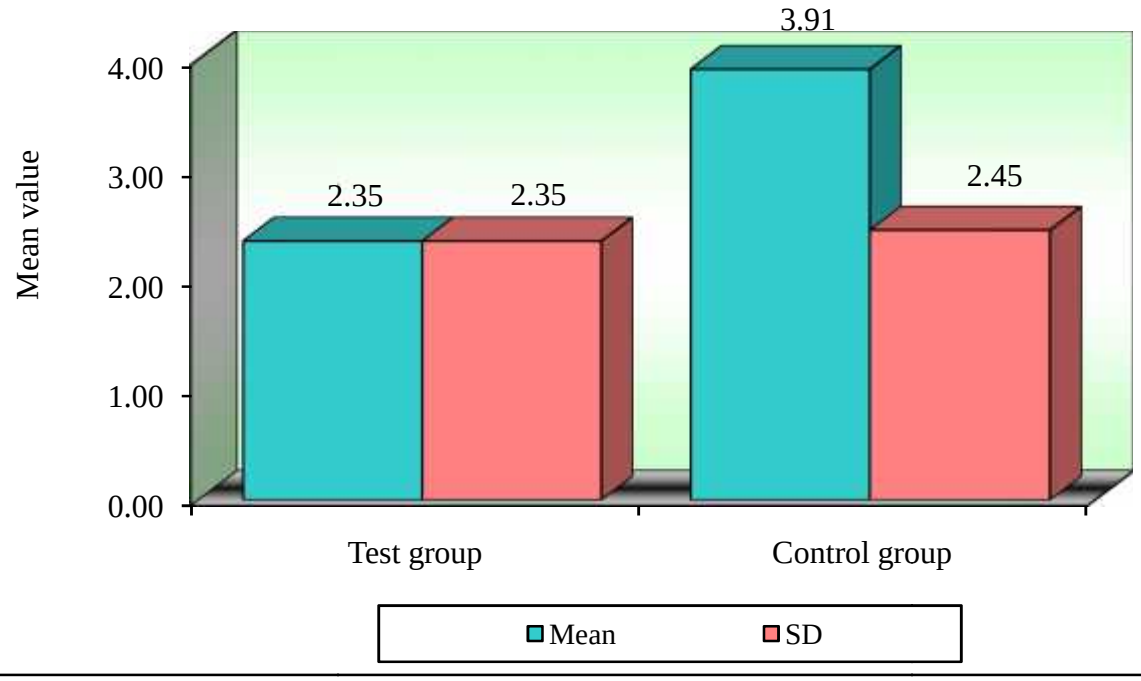


Table 9: Comparison of two groups (test and control) with convenience scores by Mann-Whitney U test.

Summery	Mean	SD	Median	IQR	Mean rank	U-value	Z-value	p-value
Test group	4.00	0.74	4.00	0.13	44.72	230.50	-4.2623	0.0001*
Control group	3.03	0.80	3.00	1.00	24.28			

*p<0.05

Figure 8: Comparison of two groups (test and control) with convenience scores

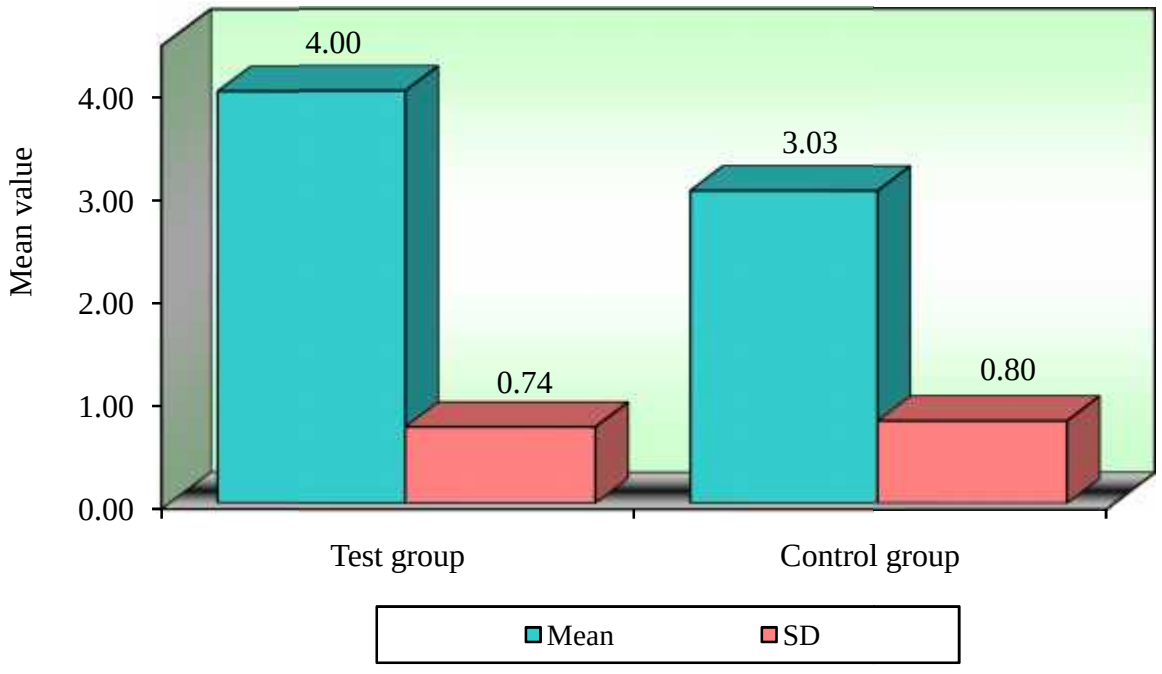
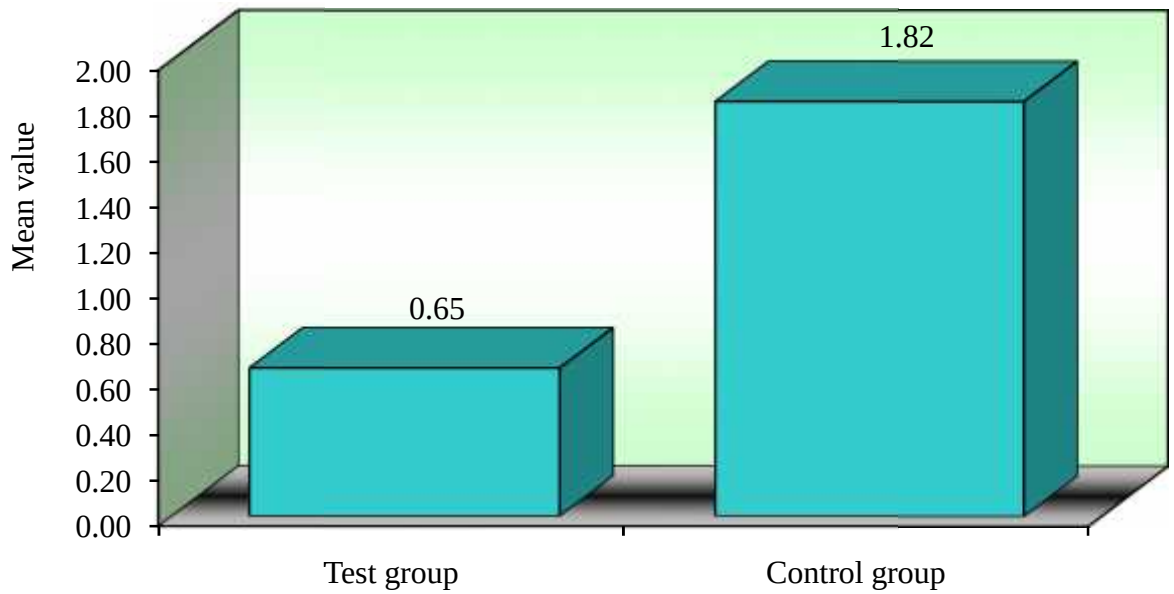


Table 10: Comparison of two groups (test and control) with number of day's patient missed the procedure in first week by Mann-Whitney U test.

Summery	Mean	SD	Median	IQR	Mean rank	U-value	Z-value	p-value
Test group	0.65	1.01	0.00	0.50	26.51			
Control group	1.82	1.59	2.00	1.13	42.49	306.50	-3.3301	0.0009*

*p<0.05

Figure 9: Comparison of two groups (test and control) with number of day's patient missed the procedure in first week



DISCUSSION

Perianal surgical wounds have been a burden to the patients due to the prolonged hospital stay in the post-operative period till a sufficient wound healing has occurred. There has been no alternative to a sitz bath and the patients have been kept for a longer period before discharging from the hospital in order to monitor the compliance of the patient towards the procedure and aid in wound recovery with regular dressings. Sitz bath has been the go-to method due to the lack of research and development of alternative management techniques primarily due to the sufficing efficacy of the procedure in relieving the symptom of pain as well as the speeding up of the wound healing due to the additives which have been added to the water.[10]

Sitz bath has certain restraints such as the patient compliance towards the procedure due to its tedious nature. Others being the slow to moderate healing process, excessive time required for the bath with multiple sittings each day, requirement of a sitz-bath tub/flat bucket for carrying out the procedure, and lack of privacy.

The ideal treatment for such post-operative wounds still remains debatable in the absence of an alternative method which would provide faster healing and better compliance to the patient.

In this study we assessed the efficacy of the colloidal silver solution spray for the management of these wounds in order to determine whether it could be a more suitable and near ideal choice.

In our study, the mean age of the patients was 43.3 ± 14.6 years, ranging from 18 to 75 years. 45.9 ± 14.7 years in the silver spray group and 40.68 ± 14.5 years in the sitz bath group. Majority of patients were in operated for Fistula in ano (35.29%),

followed by Perianal abscess (32.35%), fissure in ano (30.88%) and Fistula with Fissure in ano (1.47%).

At the end of 1 month, by the application of Mann-Whitney U test, the mean score for epithelial covering in case of Silver colloidal spray group was 3.65 whereas that in case of the Povidone-iodine sitz bath group was 3.24 (p=0.0218).

In our study, the mean post-operative VAS (Visual Analogue Scale) score by the application of Mann-Whitney U test in the Silver spray group was 2.35 and in case of sitz bath group was 3.91 (p=0.0082).

In our study, the mean Convenience score (out of 5) using Mann-Whitney U test in the case of Silver spray group was 4.0 whereas that of the Sitz bath group was 3.03 (p=0.0001).

The compliance of the patient in terms of the number of days the patient missed the procedure in the first post-operative week was calculated using Mann-Whitney U test. Out of 7(days) the mean of the number of days the patients missed the procedure was 0.65 in case of Silver spray group and 1.82 in case of Sitz bath group (p=0.0009).

We have seen from the reports of Bellinger C. G. et al. that the use of Ag in treatment of wounds has been extensively promoted, especially for burns. [40-42] Due to its role in targeting the causative pathogens while also preserving healthy tissue of the host and its commensals that are essential in maintaining a natural flora promoting wound healing. The ointment formulation has been seen to be more popular for the treatment of healing ulcers in the case of diabetic foot patients and other superficial healing ulcers over the body.

A study by Lázaro-Martínez et al. reported the usage of silver foam dressing in case of diabetic foot ulcers with acceptable results. However, due to the impaired

healing process in case of the diabetics, the time taken for a complete healing was way longer compared to the non-diabetic population. For the same reason, diabetics were excluded from this study as it would have led to a bias.[43]

With multiple studies on Ag as a suitable dressing agent are being conducted. One fact remains being reinforced is that Ag containing dressings play a vital role in modern wound managements.[65,66]To paraphrase Gunasekaran et al. in naming silver nanoparticles as 'new-age bullets' because of their large surface area to volume ratio that leads to enhancement of their efficacy. [67]

The formulation and the use of colloidal silver spray for wound healing in recent times has led to faster healing of the superficial wounds.

Besides having a very fast healing rate, the silver spray in the postoperative surgical wounds of perianal region has proved to be very convenient to the patients because it doesn't require the patient to move out of the bed for its application. The patient can apply the spray once while taking shower/bath in the morning and consequently in the bed at ease.

Our study demonstrates the superiority of the colloidal silver nanoparticles and confirms the similar findings demonstrated by the previous studies done on the bactericidal and fibroblast/ keratinoblast proliferative action of the AgNP's.[68]

As such, there are no limitations or drawbacks of silver spray. Our study demonstrates that the novel approach of silver spray application can prove to be a replacement technique in the place of sitz bath as an efficacious way of post-operative wound management.

CONCLUSION

Perianal surgical wounds have a much better healing rate with the use of topical colloidal silver spray when compared to povidone iodine sitz-bath.

The colloidal silver solution proved to be better with respect to the pain relief in patients as well. The application of the spray formulation was found to be more convenient to the patients and the compliance of the patients towards the procedure was better compared to sitz bath.

Our study demonstrates that the silver spray could be a better treatment option compared to the sitz bath.

However, a large scale study with a much larger sample size would be required for proving the hypothesis with a higher certainty.

SUMMARY

- The study was done in tertiary care KLE Dr. Prabhakar Kore hospital and MRC, Belagavi.
- In a study of 68 patients of operated perianal wounds, males comprised 73.53% and females 26.47%.
- Maximum patients belong to the age group 20 to 29 years.
- Pain in perianal region was the most common symptom followed by swelling in the perianal region and discharge from the perianal region respectively.
- Majority of patients were in operated for Fistula in ano (35.29%) , followed by Perianal abscess (32.35%), fissure in ano (30.88%) and Fistula with Fissure in ano (1.47%) .
- At the end of 1 month, by the application of Mann-Whitney U test, the mean score for epithelial covering in case of Silver colloidal spray group was 3.65 whereas that in case of the Povidone-iodine sitz bath group was 3.24 (p=0.0218).
- The mean post-operative VAS (Visual Analogue Scale) score by the application of Mann-Whitney U test in the Silver spray group was 2.35 and in case of sitz bath group was 3.91 (p=0.0082).
- The mean Convenience score (out of 5) using Mann-Whitney U test in the case of Silver spray group was 4.0 whereas that of the Sitz bath group was 3.03 (p=0.0001).
- The compliance of the patient in terms of the number of days the patient missed the procedure in the first post-operative week was calculated using Mann-Whitney U test. Out of 7(days) the mean of the number of days the patients missed the procedure was 0.65 in case of Silver spray group and 1.82 in case of Sitz bath group (p=0.0009).

Based on this research, it is found that the Silver spray application for Post-operative perianal surgical wounds is significantly superior to the conventional method of sitz bath, as:

1. Silver spray application leads to faster healing rates.
2. Patients receiving silver spray had lower average pain scores.
3. Application of silver spray was way more convenient to the patients as compared to the tedious task of performing a sitz bath.
4. The patient compliance was far better with silver spray.

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ANNEXURE I – PHOTOGRAPHS

Fig 15. Silver colloidal spray

Fig 16. Silver colloidal spray

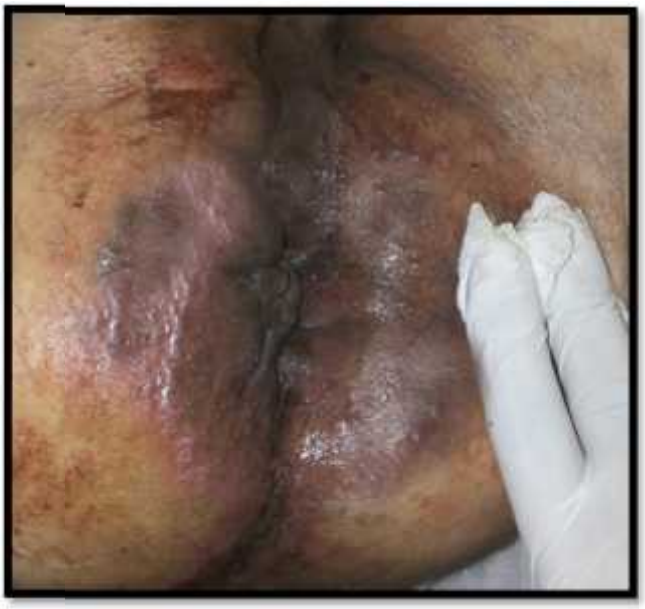

Fig 17. Preoperative Perianal abscess

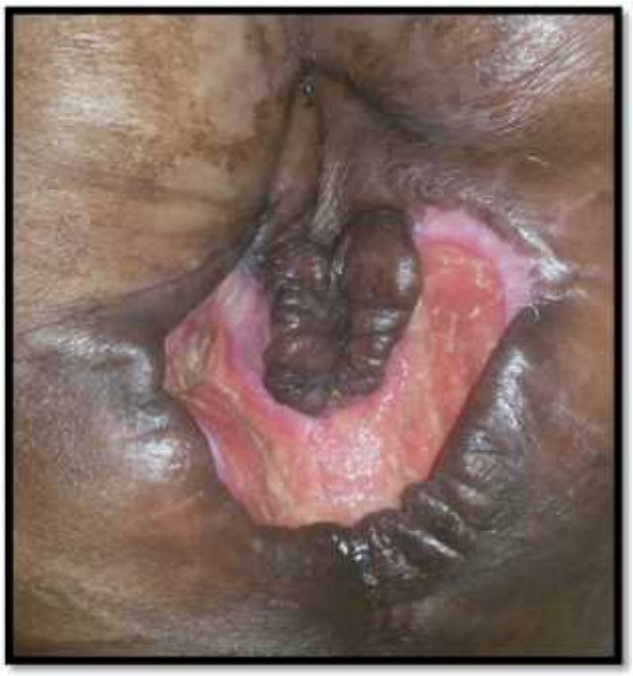

Fig 18. Post-operative Day 7

Fig 19. Post-operative day 20

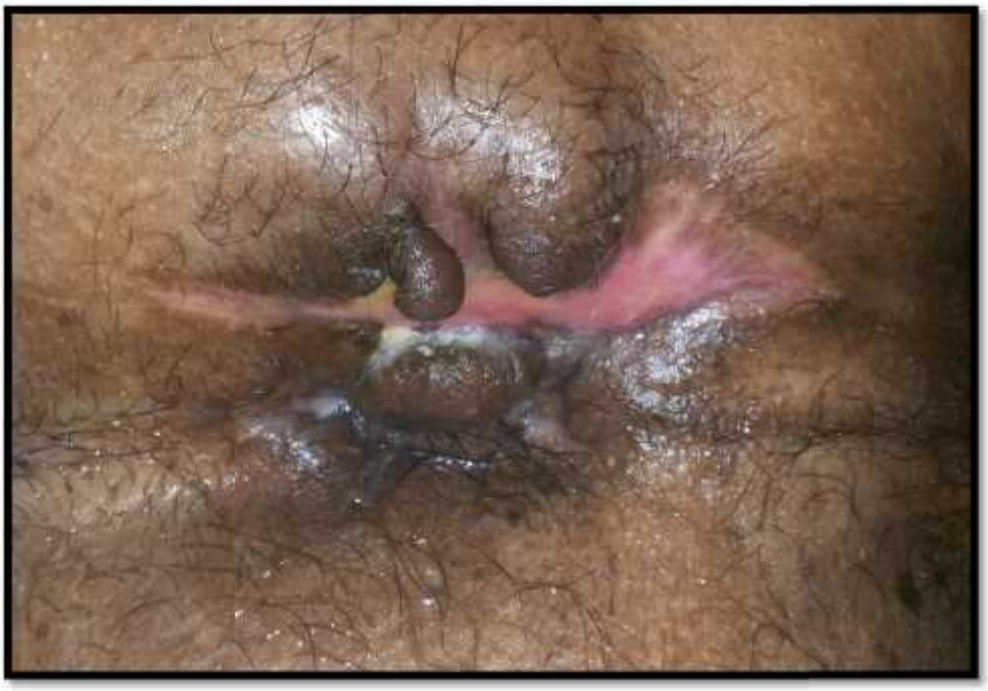

Fig 20. Post-operative Day 30

Fig 21. Ruptured Perianal abscess

ANNEXURE II

CONSENT FOR PARTICIPATION IN RESEARCH STUDY

Mr./Mrs./Miss. _____, we are requesting you to enroll yourself in study titled **"A ONE YEAR RANDOMIZED CONTROL STUDY TO COMPARE THE OUTCOMES OF PERIANAL SURGERY WOUNDS WHEN USING SILVER COLLOIDAL SOLUTION SPRAY Vs. POVIDONE IODINE SITZ-BATH AT KLES DR. PRABHAKAR KORE HOSPITAL**", conducted by REG NO. BH0118012, Post Graduate in M.S. General Surgery under the guidance of Dr. _____, Professor, Department of General Surgery, J.N. Medical College, Belagavi under KAHER, Belagavi.

Respected Sir/Madam,

We request you to participate in our study. Your participation in the research is voluntary. Your decision to participate in the study or otherwise will not affect the relationship with KLES Prabhakar Kore Hospital. If you decide not to participate, you are free to withdraw at any time. During the study, your operative outcome will be assessed by some questions.

Purpose of the study:

This research is intended to compare the post-operative wound healing, pain relief, patient convenience and patient compliance between silver colloidal solution spray and povidone iodine sitz bath. The principal investigator of the study is REG NO. BH0118012, under the guidance of Dr. _____.

Procedure Involved:

If you agree to enroll yourself in this study, your detailed history will be taken and you will be clinically examined in detail. Investigations like Hemoglobin, Total

Count, Differential Count, Platelet Count, RBS, Blood Urea, Serum Creatinine, Blood Grouping, Chest X-ray, ECG, X-Ray Fistulogram, USG Fistulogram, MR Fistulogram are required for confirmation of your diagnosis and for your pre-operative work up will be done accordingly. You will be assigned to either of the two groups for treatment, i.e., Group A – Patients receiving silver colloidal solution spray, Group B – Patients receiving Sitz Bath with povidone iodine as an additive,

By SNOSE [Sequentially Numbered Opaque Sealed Envelope].

The Wound Healing rate will be assessed by following up on the patients after discharge with the amount of epithelial covering of the wound at the end of 1 month with a scoring ranging from 0 to 4, where,

4: Complete Covering

3: 1-25% bare area

2: 26-50% bare area

1: 51-75% bare area

0: 76-100% bare area

The post-operative pain will be assessed using **Visual Analogue Scale** (VAS) at

- 48 hours
- 72 hours
- Once every week after 72 hour till complete relief.

The Convenience level will be assessed using the **Likert Scale** with a Range of 1 to 5 with increasing convenience.

The compliance of the patient towards the procedure will be assessed by documenting **how many times in a week**, the patient has missed the procedure **out of 7 days**.

Risks and Benefits:

There is no increased risk involved in being a part of this study and the complications are those which are normally anticipated. This study will help to estimate the efficacy of both the treatment regimens and provide the information as to which treatment option is superior. The results derived at the end of the study will possibly benefit all similar patients admitted in this hospital and elsewhere.

Withdrawing/removal from the study:

The participant has freedom to withdraw from the study whenever he/she wishes and without any prior notice. Even if you decline to participate, there will not be any change in the line of your management or the relationship with your doctor. You will be told about all the information that affects your decision to participate in the study. The investigator may also exclude a participant from the study at any point of time.

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:

1. In emergency to protect your rights and welfare.
2. If required by law.

Institutional/sponsors policy:

If any unforeseen complications or injury occurs during the period of study, the participant will be given treatment within the limitations of KLES Prabhakar Kore Hospital.

Financial Incentives for participation:

The participant neither gets any financial incentives during the period of study nor will be asked to pay for this study.

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 this study that can be associated with your identity will remain confidential.

Institutional Policy:

In case you have any questions related to the study, in future or in case of study related injury, you can contact:

Dr.REG NO. BH0118012	**Dr._____**
Post-Graduate, General Surgery, J. N. Medical College, KAHER, Belagavi	Professor, General Surgery, J. N. Medical College, KAHER, Belagavi

If you need any further information regarding your rights as a study participant, you may also contact:

DR. ROOPA M. BELLAD
Head of Ethical Committee,
Dept. of Paediatrics,
J. N. Medical College,
KAHER, Belagavi-590010.
Ph: 9480275601

CONSENT STATEMENT

I, Mr. /Ms. /Mrs. _____ voluntarily agree for the participation as a subject of study. By signing this consent form, I am not giving up any of my legal rights. I may withdraw from the study anytime. I am signing the consent form after having read or been read for me in my vernacular language, including the risks and the benefits and having all my questions answered.

Subject Name : _____

Signature or Left Thumb Print of Subject: _____

Witness Name: _____ Signature: _____

Investigators Name: _____ Signature: _____

Date: _____

Place: _____

अनुसंधानअध्ययनमेंभागीदारीकेलिएसहमति

श्रीश्रीमतीकुमारी ____,
हमआपकोशीर्षकसेअध्ययनमेंखुदकोनामांकितकरनेकाअनुरोधकररहेहैं"सिलवरकॉलोइडलसोल्यूशनस्प्रेबनामइस्ते मालकरतेसमयमौलिकसजेरीकेआउटपुटकीतुलनाकरनेकेलिएएकवर्षीयरैंडोमिज्डकंट्रोलस्टडीपरपोविडोनआयोडीन सिटज़ - बाथ
केएलईएसडॉ.प्रभाकरकोरेअस्पताल"डॉ.REG NO. BH0118012,
एमएसमेंस्नातकोत्तरद्वाराआयोजितडॉ.वी_____, प्रोफेसर,
जनरलसजेरीविभागकेमार्गदर्शनमेंसामान्यसजेरी, जेएनमेडिकलकॉलेज, बेलगवीकाहेर, बेलगावीकेतहत.

सम्मानितसर / मैडम,

हमआपकोहमारेअध्ययनमेंभागलेनेकाअनुरोधकरतेहैं।शोधमेंआपकीभागीदारीस्वैच्छिकहै।अध्ययनमेंभागलेनेका आपकानिर्णययाअन्यथाकेएलईएसडॉ.
प्रभाकरकोरेअस्पतालकेसाथसंबंधोंकोप्रभावितनहींकरेगा।यदिआपभागलेनेकाफैसलानहींकरतेहैं,
तोआपकिसीभीसमयवापसलेनेकेलिएस्वतंत्रहैं।अध्ययनकेदौरान,
आपकेऑपरेटिवपरिणामकामूल्यांकनकुछप्रश्नोंसेकियाजाएगा।

अध्ययनकाउद्देश्य:

इसशोधकाउद्देश्यपोस्टऑपरेटिवघावचिकित्सा, ददेराहत,
रोगीसुविधाऔरचांदीकेकोलाइडियलसमाधानस्प्रेऔरपोविडोनआयोडीनसाइटज़बाथकेबीचरोगीअनुपालनकीतुलना करनाहै।डॉ।वी।एम।पट्टनशेट्टीकेमार्गदर्शनमेंअध्ययनकेमुख्यजांचकर्तोREG NO. BH0118012हैं।

प्रक्रियाशामिल:

यदिआपइसअध्ययनमेंखुदकोनामांकितकरनेकेलिएसहमतहैं,
तोआपकाविस्तृतइतिहासलियाजाएगाऔरआपकोचिकित्सकीयरूपसेविस्तारसेजांचकीजाएगी।हेमोग्लोबिन, कुलगणना, विभेदकगणना, प्लेटलेटगणना, आरबीएस, रक्तयूरिया, सीरमक्रिएटिनिन, रक्तसमूह, छातीएक्स-रे, ईसीजी, एक्स-रेफिस्टुलोग्राम, यूएसजीफिस्टुलोग्राम,
एमआरफिस्टुलोग्रामजैसीजांचआपकेनिदानकीपुष्टिकेलिएआवश्यकहैऔरइसकेलिएआपकाप्री-ऑपरेटिववकेअपतदनुसारकियाजाएगा।आपकोइलाजकेलिएदोनोंसमूहोंमेंसेकिसीएककोसौंपाजाएगा, यानीसमूहए - चांदीकेकोलाइडियलसमाधानस्प्रेप्राप्तकरनेवालेमरीजों, समूहबी -
पिटिडोनआयोडीनकेसाथसिटबाथप्राप्तकरनेवालेमरीजोंकोएकयोजककेरूपमें,
एसएनएसईईद्वारा [अनुक्रमिकरूपसेक्रमांकितओपेकमुहरबंदलिफाफा]
1 महीनेकेअंतमेंघावकेउपकलाकवरकीमात्राकेसाथ 0 से 4
तककेस्कोरिंगकेसाथमस्तिष्कउपचारदरकामूल्यांकनरोगियोंपरकियाजाएगा, जहां,
0: पूर्णकवरिंग
1: 1-25% नंगेक्षेत्र
2: 26-50% नंगेक्षेत्र
3: 51-75% नंगेक्षेत्र

4: 76-100% नंगेक्षेत्र

पोस्ट-ऑपरेटिवददेकामूल्यांकनविजुअलएनालॉगस्केल (वीएएस) काउपयोगकरकेकियाजाएगा
-48 घंटे
72 घंटे
- 72 घंटेकेबादहरसप्ताहएकबार
पूरीराहततक
सुविधाजनकस्तरकेसाथ 1 से 5 कीरेंजकेसाथलिकर्टस्केलकाउपयोगकरकेसुविधास्तरकाआकलनकियाजाएगा।

प्रक्रियाकेप्रतिरोगीकेअनुपालनकाआकलनकियाजाएगाकिसप्ताहमेंकितनीबारदस्तावेज, रोगीने 7 दिनोंकीप्रक्रियाकोयादकियाहै।

जोखिमऔरलाभ :

इसअध्ययनकाहिस्साबननेमेंकोईजोखिमनहींहैऔरजटिलताओंवेहैंजोआमतौरपरअनुमानितहोतेहैं।यहअध्ययनउपचारउपचारदोनोंकीप्रभावकारिताकाअनुमानलगानेमेंमददकरेगाऔरजानकारीप्रदानकरेगाकिकौनसाउपचारविकल्प बेहतरहै।अध्ययनकेअंतमेंव्युत्पन्नपरिणामसंभवतःइसअस्पतालऔरअन्यजगहोंमेंभर्तीसभीसमानरोगियोंकोलाभान्वितहोंगे।

अध्ययनसेनिकालना / हटाना :

प्रतिभागीकोजबभीवहचाहेंऔरबिनाकिसीपूर्वसूचनाकेअध्ययनसेवापसलेनेकीआजादीदेताहै।यहांतक कियदिआपभागलेनेसेइनकारकरतेहैं,
तोआपकेप्रबंधनकीलाइनमेंयाआपकेडॉक्टरकेसाथसंबंधमेंकोईबदलावनहींहोगा।आपकोउनसभीसूचनाओंकेबारेमेंबतायाजाएगाजोअध्ययनमेंभागलेनेकेआपकेफैसलेकोप्रभावितकरतेहैं।जांचकतोकिसीभीसमयकिसीप्रतिभागीसेअध्ययनसेबाहरनिकलसकताहै।

गोपनीयताऔरगोपनीयता :

एकमात्रलोगयहजाननाचाहतेहैंकिआपएकशोधविषयहैं,
अनुसंधानदलकेसदस्यहैं।अनुसंधानकेदौरानआपकेद्वाराप्रदानकीगईजानकारीयाआपकेबारेमेंकोईजानकारीआपकेलिखितअनुमतिकेबिनाअन्यकोप्रकटकीजाएगी: 1. अपनेअधिकारोंऔरकल्याणकीरक्षाकेलिएआपातकालमें। 2. यदिकानूनद्वाराआवश्यकहै।

संस्थागत / प्रायोजकनीति :

यदिअध्ययनकीअवधिकेदौरानकोईअप्रत्याशितजटिलताओंयाचोटहोतीहै,
तोप्रतिभागीकोएलईएसप्रभाकरकोरेअस्पतालकीसीमाओंकेभीतरउपचारदियाजाएगा।

भागीदारीकेलिएवित्तीयप्रोत्साहन :

प्रतिभागीनतोअध्ययनकीअवधिकेदौरानकोईवित्तीयप्रोत्साहनप्राप्तकरताहैऔरनहीइसअध्ययनकेलिएभुगतानकरनेकेलिएकहाजाएगा।

परिणामप्रकाशितकरनेकेलिएप्राधिकरण:

जबशोधकेपरिणामप्रकाशितहोतेहैं, याएकसम्मेलनमेंचर्चाकीजातीहै,
तोकोईजानकारीप्रदर्शितनहींकीजाएगीजोआपकीपहचानकाखुलासाकरेगी।इसअध्ययनमेंप्राप्तकीगईकोईभीजानकारीजोआपकीपहचानसेजुड़ीहोसकतीहैवहगोपनीयरहेगी।

REG NO. BH0118012 डॉ._____

डॉ. रुपाएमबेलाड
नैतिकसमितिकेप्रमुख,
पेडियाट्रिक्सविभाग,
जेएनमेडिकलकॉलेज,
काहेर, बेलगावी-590010.
फोननंबर 9480275601

ರಸಚ್ನ್ಡನಲ್ಲಪಾಲ್ಗೊಳ್ಳುವಿಕಯಒಪ್ಪಿಗ

ಶ್ರೀ / ಶ್ರೀಮತಿ / ಮಿ . _____,

ನಾವುಹಸರನಅಧ್ಯಯನದಲ್ಲನಿಮ್ಮನ್ನುಸೇರಿಸಕೂಳ್ಳಬೇಕಂದುನಾವುಮನವಮಾಡುತ್ತಿದ್ದೇವ"ಸರಯಿರ್ಕೂಲೂಯ್ದಾಲ್ಬರಂಹಾರಸ್ಯೇ ವರ್ಸಸ್ಬಳಸುವಾಗಪರಿಯಾನಲ್ಸರ್ಜರಿಯಫಲಿತಾಂಶಗಳನ್ನುಹೋಲಿಸಲುಒಂದುವರ್ಷದಯಾದೃಚ್ಛಕನಿಯಂತ್ರಣಅಧ್ಯಯನ. ಪೂಲಡೋನಾಐಯೋಡಿನ್ಸುಟ್ಟಾ-ಬಾತಾಅಟ್ಕಿಎಲಾಇಎಸ್ಟಾ. ಪ್ರಭಾಕರ್ಕೋರೆಆಸ್ಪತ್ರೆಯಲ್ಲಿREG NO. BH0118012ಅವರುನಡಸದಅಧ್ಯಯನ. ಎಂ. ಎಸ್. ಜನರಲ್ಸರ್ಜರಿಯಲ್ಲಪೋಸ್ಟ್ದವೀಧರರುಡಾ. _____, ಜನರಲ್ಸರ್ಜರಿಯಇಲಾಖೆಪ್ರೊಫೆಸರ್, ಅವರಮಾರ್ಗದರ್ಶನದಲ್ಲಿ, ಜೆಎನ್ಎನ್ಮೆಡಿಕಲ್ಕಾಲೇಜ್, ಕಾಹೆರ್, ಬೆಳಗಾವಿ.

ಗೌರವಾನ್ವಿತಸರ್ / ಮಡಮ್,

ನಮ್ಮಅಧ್ಯಯನದಲ್ಲಭಾಗವಹಿಸಲುನಾವುನಿಮ್ಮನ್ನುವಿನಂತಿಸುತ್ತೇವ.
ಸಂಶೋಧನೆಯನಿಮ್ಮಭಾಗವಹಿಸುವಿಕೆಸ್ವಯಂಪ್ರೇರಿತವಾಗಿರುತ್ತದ.
ಈಅಧ್ಯಯನದಲ್ಲಿಭಾಗವಹಿಸಲುಅಥವಾನಿಮ್ಮನಿರ್ಧಾರವನ್ನುಕವಲ್ಇಎಸ್ಐಭಾಕರ್ಕೋರೆಆಸ್ಪತ್ರೆಯಮೇಲಪರಿಣಾಮಬೀರುವುದಲ್ಲ. ನೀವುಭಾಗವಹಿಸಬಾರದೆಂದುನಿರ್ಧರಿಸಿದರೆ, ನೀವುಯಾವುದೇಸಮಯದಲ್ಲಿಹಿಂಪಡೆಯಲುಸ್ವತಂತ್ರರಾಗಿರುತ್ತಾರೆ. ಅಧ್ಯಯನದಲ್ಲಿ, ನಿಮ್ಮಕಾರ್ಯಾತ್ಮಕಫಲಿತಾಂಶವನ್ನುಕೆಲವುಪ್ರಶ್ನೆಗಳಿಂದಮೌಲ್ಯಮಾಪನಮಾಡಲಾಗುತ್ತದೆ.

ಅಧ್ಯಯನದಉದ್ದೇಶ:

ಈಸಂಶೋಧನೆಯಿಆಪರೇಟಿವ್ನಾಯಿದಗುಣಪಡಿಸುವಿಕ, ನೋವುಪರಿಹಾರ, ರೋಗಿಯಅನುಕೂಲತೆಮತ್ತುಬಳ್ಳಿಕೋಲಾಡಲ್ಬರಿಹಾರಸ್ಯೇಮತ್ತುಪೂವಿಡೋನಾಅಯೋಡಿನ್ಸುಟ್ಟಾ್ಚನದನಡುವನರೋಗಿಯಅನುಸರಣೆಗಹೋಲಿಸಲುಉದ್ದೇಶಿಸಿದೆ. ವಿವಿಂಪಟ್ಟನ್ಯೆಟ್ಟಿಅವರಮಾರ್ಗದರ್ಶನದಲ್ಲಿREG NO. BH0118012ಅವರುಈಅಧ್ಯಯನದಪ್ರಮುಖಸಂಶೋಧಕರಾಗಿದ್ದಾರೆ .

ಕಾರ್ಯವಿಧಾನಕ್ಕೆಒಳಪಟ್ಟದ:

ಈಅಧ್ಯಯನದಲ್ಲಿನಿಮ್ಮನ್ನುತೊಡಗಿಸಿಕೊಳ್ಳಲುನೀವುಒಪ್ಪಿಕೂಂಡರ,
ನಿಮ್ಮವಿವರವಾದಇತಿಹಾಸವನ್ನುತೆಗೆದುಕೊಳ್ಳಲಾಗುವುದುಮತ್ತುನೀವುಪ್ರಾಯೋಗಿಕವಾಗಿವಿವರವಾಗಿಪರಿಶೀಲಸಲಾಗುವುದು.
ನಿಮ್ಮರೋಗನಿದಾನದದೃಢೀಕರಣಕ್ಕೆಸಂಬಂಧಸದಂತಹಮೋಗ್ಲೋಬನ್, ಟೂಡಿಲ್ಕ್ಂಟಾ, ಡಿಫರನ್ಷಿಯಲ್ಕ್ಂಟಾ, ಪ್ಲೇಟ್ಲೆಟ್ಕೌಂಟ್, ಆರ್ಬಿಎಸ್, ಬ್ಲಡ್ಯೂರಿಯಾ, ಸೀರಮ್ಕ್ರಿಯೆಟಿನೈನ್, ಬ್ಲಡ್ಗ್ರೂಪಿಂಗ್, ಚೆಸ್ಟ್ಎಕ್ಸ್-ರೇ, ಇಸಿಜಿ, ಎಕ್ಸ್-ರೇಫಿಸ್ಟ್ಯೂಲಾಗ್ರಾಮ್, ಯುಎಸ್ಜಿಫಿಸ್ಟ್ಯೂಲಾಗ್ರಾಮ್, ಎಮ್ಆರ್ಫಿಸ್ತುಲೋಗ್ರಾಮ್ನಂತಹತನಿಖೆಗಳುಅಗತ್ಯವಾಗಿವೆ.
ನಿಮ್ಮಪೂರ್ವಕಾರ್ಯಾಚರಣಾಕಾರ್ಯವುಅನುಗುಣವಾಗಿಮಾಡಲಾಗುತ್ತದೆ.
ಚಿಕಿತ್ಸೆಯಲ್ಲಿಎರಡುಗುಂಪಿನಲ್ಲಿನಿಮ್ಮನ್ನುನಿಯೋಜಿಸಲಾಗುವುದು, ಅಂದರೆ. ಗುಂಪುಎ -
ಬೆಳ್ಳಿಕೋಲಾಡಲ್ಬರಿಹಾರಸ್ಯೇಪಡೆದರೋಗಿಗಳು, ಗ್ರೂಪ್ಬಿ -
ಪೂವಿಡೋನ್ಅಯೋಡಿನ್ಟೂತೆಯಲ್ಲಿಸಿಟ್ಟಾ್ಚತ್ಸೀಕರಿಸುವರೋಗಿಗಳುಸಂಯೋಜಕವಾಗಿ,
ಸ್ಲೀಪ್ [ಅನುಕ್ರಮವಾಗಿಸಂಖ್ಯೆಯಅಪಕ್ಯಾಮುಚ್ಚಿದಎನ್ವೆಲಪ್] .

ಗಾಯಗೊಂಡಎಪಥೇಲಯಿಲ್ಕವಚವನ್ನು । ತಂಗಳಕೂನಯಿಲ್ಲ 0 ರಂದ 4
ರವರೆಗಿನಗಾಯದೊಂದಿಗೆಉಂಟಾದನಂತರರೋಗಿಗಳಮೇಲಅನುಸರಿಸುವುದರಮೂಲಕಗಾಯದಗುಣಪಡಿಸುವಪ್ರಮಾಣವನ್ನು
ಮೌಲ್ಯಮಾಪನಮಾಡಲಾಗುತ್ತದೆ.

0: ಕಂಪ್ಲೀಟ್ಕವರ್ಕಂಗ್
1: 1-25% ಬೇರ್ಪ್ರದೇಶ
2: 26-50% ಬೇರ್ಪ್ರದೇಶ
3: 51-75% ಬೇರ್ಪ್ರದೇಶ
4: 76-100% ಬೇರ್ಪ್ರದೇಶ

ಎಷಯಲ್ಅನಲಾಗ್ಸ್ಕೀಲ್ (ಎಎಎಸ್) ಯಿಬಳಶಸ್ತ್ರಚಕತ್ಸೆಯಿನಂತರದನೋವನ್ನುಮೌಲ್ಯಮಾಪನಮಾಡಲಾಗುತ್ತದ
- 48 ಗಂಟೆಗಳ
- 72 ಗಂಟೆಗಳ
- 72 ಗಂಟೆಗಳನಂತರಪ್ರತಿವಾರಕ್ಕಒಮ್ಮೆ
ಸಂಪೂರ್ಣಪರಿಹಾರತನಕ.
ಅನುಕೂಲಕರಮಟ್ಟವನ್ನುಹೊಂದಿರುವ 1 ರಂದ 5
ವ್ಯಾಪ್ತಿಯೊಂದಿಗೆಲ್ಕಟ್ಸ್ಕೇಲ್ಬಳಸಿಕೊಂಡುಅನುಕೂಲಕರಮಟ್ಟವನ್ನುಮೌಲ್ಯಮಾಪನಮಾಡಲಾಗುತ್ತದ.

ಕಾರ್ಯವಿಧಾನದಕಡಗರೋಗಿಯಿಅನುಸರಣೆಯನ್ನುವಾರದಲ್ಲಎಷ್ಟುಬಾರಿದಾಖಲಿಸುವಮೂಲಕಮೌಲ್ಯಮಾಪನಮಾಡಲಾಗುವು
ದು, ರೋಗಿಯು 7 ದಿನಗಳಏರಗಕಾರ್ಯವಿಧಾನವನ್ನುತಪ್ಪಿಸಿಕೊಂಡಿದ್ದಾನ.

ಅಪಾಯಗಳುಮತ್ತುಲಾಭಗಳು:

ಈಅಧ್ಯಯನದಒಂದುಭಾಗದಲ್ಲಹಚ್ಚಿದಅಪಾಯವುಇಲ್ಲಮತ್ತುಸಾಮಾನ್ಯವಾಗಿಸಮಸ್ಯೆಗಳನ್ನುನಿರೀಕ್ಷಿಸುವಂತಹವುಗಳು.
ಈಅಧ್ಯಯನವುಚಿಕಿತ್ಸೆಯನೆಯಮಗಳಪರಿಣಾಮಕಾರಿತ್ವವನ್ನುಅಂದಾಜುಮಾಡಲುಸಹಾಯಮಾಡುತ್ತದಮೆತ್ತುಯಾವಚಕತ್ಸೆಯಿಕ
ಯ್ಕೆಯುಉತ್ತಮವಾದುದಿಂದುಮೌಹಿತೆನೀಡುತ್ತೆದ.
ಅಧ್ಯಯನದಕೂನೆಯಲ್ಲಿಪಡದಿಫಲಿತಾಂಶಗಳುಈಕ್ಷೇತ್ರಯಿಲ್ಲಮತ್ತುಬೇರಡೆಇರುವಎಲ್ಲಾರೀತಿಯರೋಗಗಳಗಾಪ್ರಯೋಜನಕಾರ
ಯಾಗುತ್ತವ.

ಅಧ್ಯಯನದಹಿಂತಗದುಕೂಳ್ಳುವಿಕ / ತಗದುಹಾಕುವಿಕ:

ಪಾಲ್ಗೊಳ್ಳುವವರುಅವನು /
ಅವಳುಬಯಸಿದಾಗಲೆಲ್ಲಮತ್ತುಯಾವುದೇಮುಂಚನಸೂಚನೆಇಲ್ಲದಹಿಂಪಡೆಯಲುಸ್ವಾತಂತ್ರ್ಯವನ್ನುಹೊಂದಿದ್ದಾನ.
ನೀವುಭಾಗವಹಿಸಲುನಿರಾಕರಿಸಿದರೂಸಹ,
ನಿಮ್ಮನಿರ್ವಹಣೆಯಸಾಲಿನಲ್ಲಿಅಥವಾನಿಮ್ಮವೈದ್ಯರೊಂದಿಗಿನಸಂಬಂಧದಲ್ಲಯಾವುದೇಬದಲಾವಣೆಗಳಿರುವುದಲ್ಲ.
ಅಧ್ಯಯನದಲ್ಲಿಪಾಲ್ಗೊಳ್ಳಲುನಿಮ್ಮನಿರ್ಧಾರವನ್ನುಪರಿಣಾಮಬೀರುವಎಲ್ಲಾಮಾಹಿತಿಯಕುರಿತುನಿಮಗಹೇಳಲಾಗುತ್ತದ.
ತನಿಖಾಧಿಕಾರಿಯುಯಾವುದೇಸಮಯದಲ್ಲಾದರೂಅಧ್ಯಯನದಿಂದಪಾಲ್ಗೊಳ್ಳುವವರನ್ನುಕೂಡಾಹೊರಗಿಡಬಹುದು.

ಗೌಪ್ಯತಮತ್ತುಗೋಪ್ಯತ:

ನೀವುಸಂಶೋಧನಾವಿಷಯವಂದುತಳದರುವವಿಕ್ಕಕಜನರುಸಂಶೋಧನಾತಂಡದಸದಸ್ಯರಾಗಿದ್ದಾರೆ.
ಸಂಶೋಧನೆಯಿಸಂದರ್ಭದಲ್ಲಿನಿಮಗಅಥವಾಮಾಹಿತಿಬಗ್ಗೆಯಾವುದೇಮಾಹಿತಿಇಲ್ಲದಿದ್ದರೆನಿಮ್ಮಲಿಖಿತಅನುಮತಿಯಿಲ್ಲದಇ
ನ್ನೆಂದಿಗೂಬಹಿರಂಗಪಡಿಸಲಾಗುವುದು:

1. ನಿಮ್ಮಹಕ್ಕುಗಳನ್ನುಮತ್ತುಕಲ್ಯಾಣವನ್ನುರಕ್ಷಿಸಲುತುರ್ತುಪರಿಸ್ಥಿತಿಯಿಲ್ಲ.
2. ಕಾನೂನಿನಿಂದಅಗತ್ಯವಿದ್ದರೆ.

ಸಾಂಸ್ಥಿಕ / ಪ್ರಾಯೋಜಕನೀತಿ:

ಅಧ್ಯಯನದಅವಧಿಯಲ್ಲಿಯಾವುದೇಅನಿರೀಕ್ಷಿತತೊಡಕುಗಳುಅಥವಾಗಾಯಗಳುಸಂಭವಿಸಿದರೆ,
ಭಾಗವಹಿಸುವವರಿಗೆಕವಲ್ಇಎಸ್ಐಭಾಕರ್ೋರೆಆಸ್ಪತ್ರೆಯಮಿತಿಗಳಲ್ಲಿಚಿಕಿತ್ಸೆನೀಡಲಾಗುವುದು.

ಭಾಗವಹಿಸುವಿಕೆಗಾಗಿಹಣಕಾಸಿನಉತ್ತೇಜಕಗಳು:

ಪಾಲ್ಗೊಳ್ಳುವವರಅಧ್ಯಯನದಅವಧಿಯಲ್ಲಿಯಾವುದೇಹಣಕಾಸಿನಪ್ರೋತ್ಸಾಹವಿನ್ನುಪಡೆಯುವುದಲ್ಲಅಥವಾಈಅಧ್ಯಯನಕ್ಕಾಗಿಪಾ
ವತಿಸಲುಕೇಳಲಾಗುವುದಲ್ಲ.

ಫಲಿತಾಂಶಗಳನ್ನುಪ್ರಕಟಿಸಲುಅಧಿಕಾರ :

ಸಂಶೋಧನೆಯಫಲಿತಾಂಶಗಳನ್ನುಪ್ರಕಟಿಸಿದಾಗಅಥವಾಸಮ್ಮೇಳನದಲ್ಲಚರ್ಚಿಸಿದಾಗ,
ನಿಮ್ಮಗುರುತನ್ನುಬಹಿರಂಗಪಡಿಸುವಯಾವುದೇಮಾಹಿತಿಯನ್ನುಪ್ರದರ್ಶಿಸಲಾಗುವುದಿಲ್ಲ.
ನಿಮ್ಮಗುರುತನ್ನುಹೊಂದಿರುವಈಅಧ್ಯಯನದಲ್ಲಿಪಡೆದಯಾವುದೇಮಾಹಿತಿಗೌಪ್ಯವಾಗಿರುತ್ತದೆ.

ಡಾ. REG NO.BH0118012 ಡಾ._____

ದೂರವಾಣಿಸಂಖ್ಯೆ: ದೂರವಾಣಿಸಂಖ್ಯೆ:

ಡಾರೂಪಾಎಂ. ಬೆಲ್ಲಾದ್
ನೈತಿಕಸಮಿತಿಯಮುಖ್ಯಸ್ಥ,
ಪೀಡಿಯಾಟ್ರಿಕ್ಸ್ ಭಾಗ,
ಜೆ.ಎನ್. ಮೆಡಿಕಲ್ಕಾಲೇಜ್,
ಕಾಹೆರ್, ಬೆಳಗಾವಿ-590010.
ದೂರವಾಣಿಸಂಖ್ಯೆ: 9480275601

संशोधनअभ्यासातसहभागीहोण्यासाठीसंमती

मिस्टर / श्रीमती / मिस. _____,
आम्हीआपणासशीर्षकानेअभ्यासातनावनोंदणीकरण्यासविनंतीकरीतआहोत
"एकवर्षोचानियंत्रितनियंत्रणाचाअभ्यासशिल्लककलोडिअलसोल्यूशनस्प्रेवि. एस.
वापरतानापारंपारिकसजेरीच्याउद्रेकांमधूनबाहेरपडण्याचीतुलनाकरा. पोल्विडेनआयोडीनसिल्झ-
बाथकेएलईएसप्रभाकरकोरेहॉस्पिट" REG NO. BH0118012, एम.एस.मधीलस्नातकोत्तरडॉ.
_____यांच्यामार्गदर्शनाखालीसामान्यशस्त्रक्रिया, जनरलसर्जरीविभागाचेप्राध्यापक,
जेएनमेडिकलकॉलेज, बेलगवीकाहेर, बेलागवीअंतर्गत.

आदरणीयसर / मॅडम,

आम्हीआपल्याअभ्यासातसहभागीहोण्यासाठीविनंतीकरतो. संशोधनमध्येआपलेसहभागस्वैच्छिकआहे.
याअभ्यासातसहभागीहोण्याचातुमचानिर्णयकिंवाअन्यथाकेएलईएसप्रभाकरकोरेहॉस्पिटलशीसंबंधितसंबंधांवरकोण
ताहीपरिणामहोणारनाही. आपणसहभागनघेण्याचेठरविल्यासआपणकोणत्याहीवेळीमागेघेण्यासमोकळेआहात.
अभ्यासादरम्यान, आपल्यापरिचालनात्मकपरिणामांचेकाहीप्रश्नांचेमूल्यांकनकेलेजाईल.

अभ्यासाचाउद्देशः

हेसंशोधनऑपरेटरच्याजखमेच्याउपचार, वेदनाआराम,
रुग्णाचीसोयआणिचांदीच्याकोलोइडलसोल्युशनस्प्रेआणिपोव्हिडोनआयोडीनसिटझबाथयांच्यातीलसहनशीलतेचीतु
लनाकरण्याचाआहे डॉ_____,यांच्यामार्गदर्शनानुसारREG NO.
BH0118012याअभ्यासाचेमुख्यतपासकआहेत.

प्रक्रियासमाविष्ट

आपणयाअभ्यासातआपलेनावनोंदविण्याससहमतअसल्यास,
आपलातपशीलवारइतिहासघेण्यातयेईलआणिआपल्यालावैद्यकीयदृष्ट्यातपशीलवारपणेतपासणीकेलीजाईल.
हेमोग्लोबिन, टोटलकाउंट, डिफॉल्टकाउंटर, प्लेटलेटकाउंट, आरबीएस, ब्लडयूरिया,सीरमक्रिएटिनिन, ब्लडग्रुपिंग,
चेस्टएक्स-रे, ईसीजी, एक्स-रेफिस्टलोग्राम, यूएसजीफिस्टलोग्राम,
एमआरफिस्टलोग्रामसारख्यातपासणीआपल्यानिदानआणिपुष्टीकरणासाठीआवश्यकआहेत. आपलेपूर्व-
कामकाजकार्येत्यानुसारकेलेजाईल. आपल्यालाउपचारांसाठीदोनगटांपैकीएकम्हणूननेमण्यातयेईल, म्हणजेग्रुप -
रजनीकोलोडायडसोल्युशनस्प्रेप्राप्तकरणार्यांग्रुपबी - ग्रुपबी -
सिड्सबाथप्राप्तकरणार्यांरुग्णांनापोव्हीडोनआयोडीनसहजोडकम्हणून,
SNOSE द्वारा [अनुक्रमांकितक्रमांकितओपेकसीलबंदलिफाफा].

1 महिन्याच्याशेवटीजखमेच्याउपशामकआच्छादनाने 0 ते 4
पर्यंतस्कोअरिंगसहस्त्रावझाल्यानंतररुग्णांचीपाठपुरावाकरूनजखमेच्याहीलिंगरेटचेमूल्यांकनकेलेजाईल.

0: पूर्णकव्हरिंग
1: 1-25% बेअरक्षेत्र
2: 26-50% बेअरएरिया

3: 51-75% बेअरएरिया

4: 76-100% बेअरएरिया

पोस्ट-ऑपरेटिव्हवेदनाचीव्हयूज्युअलॲनालॉजस्केल (व्हीएएस) वापरूनमूल्यांकनकेलेजाईल

48 तास

72 तास

72 तासांनंतरप्रत्येकआठवड्यातएकदा

संपूर्णेमदतपर्यंत

सुविधासुविधेसह 1 ते 5 च्यारेंजसहलिकर्टस्केलवापरूनसुविधापातळीचेमूल्यांकनकेलेजाईल.

प्रक्रियेच्यादिशेनेरुग्णाच्याअनुपालनाचेमूल्यांकनआठवड्यातूनकितीवेळादस्तऐवजीकरणकरूनकेलेजाईल. रुग्णा
7 दिवसांपासूनप्रक्रियारद्दकेलीआहे.

धोकेआणिफायदे

याअभ्यासाचाएकभागबनण्यातगुंतलेलीकोणतीहीजोखीमनसतेआणिसामान्यतःअपेक्षितअसलेल्याजटिलताअस
तात.

याअभ्यासामुळेउपचारांच्यादोन्हीनियमांच्याप्रभावीतेचाअंदाजघेण्यासमदतहोईलआणिमाहितीचापर्यायकोणताअ
सावायाबद्दलमाहितीप्रदानकरण्यातमदतहो .

अभ्यासाच्याशेवटीकाढलेल्यापरिणामांमुळेयारुग्णालयातआणिइतरत्रभरलेल्यासवेरुग्णांनाशक्यतोफायदाहोईल.

अभ्यासमागेघेणे / काढणे:

जेव्हाजेव्हातो / तिलाइच्छाअसेलआणिपूर्वसूचनानदेतासहभागीहोण्यासभागघेण्यासभागघेतील.
जरीआपणभागघेण्यासनकारदिलाअसलातरीआपल्याव्यवस्थापनाच्याओळीतकिंवाआपल्याडॉक्टरांमधीलसंबंधांम
ध्येकोणतेहीबदलहोणारनाहीत.

अभ्यासातभागघेण्यासा आपल्यानिर्णयावरपरिणामकरणायासवेमाहितीबद्दलआपल्यालासांगितलेजाईल.

अन्वेषककोणत्याहीवेळीअभ्यासातूनकोणत्याहीअभ्यासातबहिष्कारकरूशकतो.

गोपनीयताआणिगुप्तता:

आपणसंशोधनविषयआहातहेकेवळलोकांनाचमाहितआहेकीतेसंशोधनकार्यसंघाचेसदस्यआहेत.

आपल्याबद्दलकोणतीहीमाहितीकिंवासंशोधनदरम्यानआपल्याद्वारेप्रदानकेलेलीमाहितीआपल्यालिखितपरवानगी
शिवायइतरांनाउघडकेलीजाणारनाही.

1. आपल्याअधिकारांचेआणिकल्याणाचेरक्षणकरण्यासाठीआणीबाणीमध्ये.
2. कायद्यानुसारआवश्यकअसल्यास.

संस्थात्मव / प्रायोजकधोरण:

अभ्यासाच्याकालावधीतकोणतीहीअनपेक्षितसमस्याकिंवादुखापतझाल्यास.

सहभागींनाकेएलईएसप्रभाकरकोरेहॉस्पिटलच्यामर्यादांमध्येउपचारदेण्यातयेईल.

सहभागासाठीआर्थिकप्रोत्साहनः

अभ्यासादरम्यानअभ्यासाच्याकालावधीदरम्यानकोणतेहीआर्थिकप्रोत्साहनमिळतनाहीतकिंवायाअभ्यासासाठीदेय करण्याससांगितलेजाणारनाही.

परिणामप्रकाशितकरण्यासाठीअधिकृतताः

जेव्हाशोधपरिणामांचेप्रकाशनकेलेजातेकिंवाकॉन्फरन्समध्येचर्चाकेलीजातेतेव्हाकोणतीहीमाहितीप्रदर्शितकेलीजा णारनाहीजीआपलीओळखउघडकरेल.

आपल्याअभ्यासाशीसंबद्धअसलेल्यायाअभ्यासातप्राप्तकेलेलीकोणतीहीमाहितीगोपनीयराहील.

REG NO. BH0118012 डॉ_____

दूरध्वनीक्रमांक : दूरध्वनीक्रमांक:

डॉ. रूपाएमबेलाड
नैतिकसमितीचेप्रमुख,
पेडियट्रिक्सविभाग,
जे.एन. मेडिकलकॉलेज,
काहेर, बेलागवी- 590010.
फोनक्रमांक 9480275601

ANNEXURE III

ETHICAL CLEARANCE CRIFITICATE

K.L.E. ACADEMY OF HIGHER EDUCATION AND RESEARCH
(Deemed – to- be- University)
Accredited 'A' Grade by NAAC (2nd Cycle) Placed in Category 'A' by MHRD (GoI)
JAWAHARLAL NEHRU MEDICAL COLLEGE,
NEHRU NAGAR, BELAGAVI-590010 (KARNATAKA-INDIA)
Website: http//www.jnmc.edu
E-Mail : dome@jnmc.edu
Phone: (+91-(0)831 Office : 2472550
Principal: 2471701
Fax No. +91 (0)831 – 2470759

Ref: MDC/DOME/ **Date: 24/11/2018**

To,

REG NO. BH0118012
PG student in Surgery,
J.N.Medical College,
BELAGAVI.

Sub: Institutional Ethical Clearance for the study.

With reference to the above, we wish to inform you that your proposed research project titled **"A ONE YEAR RANDOMIZED CONTROL STUDY TO COMPARE THE OUTCOMES OF PERIANAL SURGERY WOUNDS WHEN USING SILVER COLLOIDAL SOLUTION SPRAY VS. POVIDONE IODINE SITZ-BATH AT KLES DR. PRABHAKAR KORE HOSPITAL",** is ethical and justifiable. The proposed research project has been cleared by the JNMC Institutional Ethics Committee on Human Subjects Research.

(Dr. Arathi Darshan)
Member Secretary
JNMC Institutional Ethics Committee
on Human Subjects Research,
J.N.Medical College, Belagavi.

(Dr. Roopa M Bellad)
Chairman,
JNMC Institutional Ethics Committee
on Human Subjects Research,
J.N.Medical College, Belagavi.

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ANNEXURE IV - PROFORMA

PROFORMA / QUESTIONNAIRE TO BE USED FOR DATA COLLECTION

The proposed proforma / questionnaire to be used for data collection for the study titled **"A ONE YEAR RANDOMIZED CONTROL STUDY TO COMPARE THE OUTCOMES OF PERIANAL SURGERY WOUNDS WHEN USING SILVER COLLOIDAL SOLUTION SPRAY Vs POVIDONE IODINE SITZ-BATH AT KLES DR. PRABHAKAR KORE HOSPITAL"** is as:

Group:

Name: IP no.:

Sex: Age:

Address: Religion:

Education: Date of admission:

Occupation: Date of discharge:

CHIEF COMPLAINTS:

HISTORY OF PRESENTING COMPLAINTS:

PAST HISTORY:

PERSONAL HISTORY:

FAMILY HISTORY:

GENERAL PHYSICAL EXAMINATION:

Built and Nourishment:

Weight:

Pallor / Icterus / Cyanosis / Clubbing / Edema / Lymphadenopathy

Vital Signs: PR: /min; BP: mm Hg; RR: /min; Febrile/Afebrile

SYSTEMIC EXAMINATION:

Abdomen:

Inspection:

Palpation:

Percussion:

Auscultation:

Cardio Vascular System:

Respiratory System:

CLINICAL IMPRESSION:

INVESTIGATIONS:

Hb: Total Leucocyte Count: Platelet count:

Random blood sugar :

Blood Group:

Blood urea: Sr. Creatinine:

PT/INR:

Urine routine and microscopy:

HIV: HBsAg:

ECG:

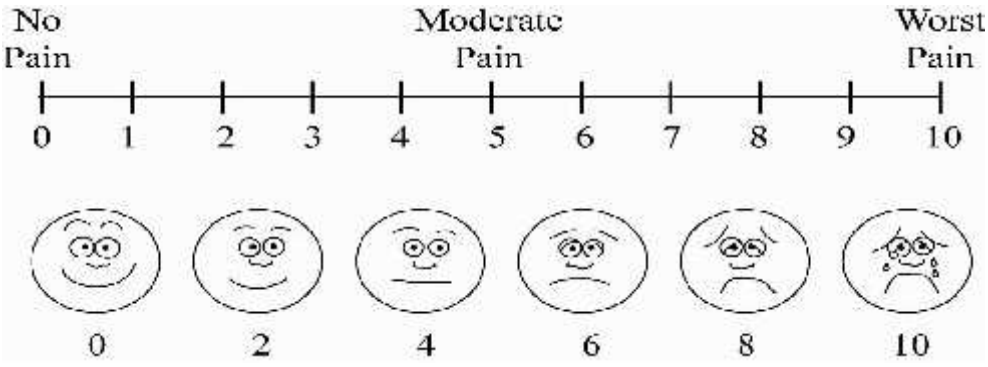
Chest Xray:

USG/CT/MR Fistulogram:

1. AMOUNT OF EPITHELIAL COVERING AT THE END OF 1 MONTH?

_____ (SCORE 0-4)

2. **POST OPERATIVE PAIN SCORE ACCORDING TO VISUAL ANALOGUE SCALE*:***



3. CONVENIENCE TO THE PATIENT:

4. NUMBER OF TIMES, THE PATIENT MISSED THE PROCEDURE:

_____DAYS OUT OF 7 DAYS

TEST SAMPLES (SILVER SPRAY)

Serial No.	IP Number	Age	Sex	Religion	Diagnosis	Surgery	Epithelial covering score at the end of 1 month (0-4)	Post-op VAS Pain Score (0-10)	Convenience score (0-5)	Number of DAYS patient missed the procedure IN FIRST WEEK
1	987793	47	M	HINDU	FISTULA IN ANO	FISTULECTOMY ON 07.12.19	3	7	4	2
2	950736	51	M	HINDU	FISTULA IN ANO	FISTULECTOMY ON 08.06.19	4	5	4	1
3	964550	37	M	HINDU	FISTULA IN ANO	FISTULECTOMY ON 21.08.19	4	3	3	3
4	966061	55	M	HINDU	PERIANAL ABSCESS	I & D ON 29.08.19	2	7	2	4
5	950662	20	F	HINDU	PERIANAL ABSCESS	I & D ON 11.06.19	3	2	4	0
6	990785	44	M	HINDU	FISTULA IN ANO	FISTULECTOMY ON 23.12.19	4	4	4	0
7	947931	36	M	HINDU	FISTULA IN ANO	FISTULECTOMY ON 04.06.19	4	2	3	1
8	975823	35	M	HINDU	FISTULA IN ANO	FISTULECTOMY ON 14.10.19	4	2	4	2
9	948486	23	M	MUSLIM	FISTULA IN ANO	FISTULECTOMY ON 29.05.19	4	1	4	0
10	972807	25	F	HINDU	FISSURE IN ANO	FISSURECTOMY ON 25.09.19	4	0	5	0
11	969417	27	M	HINDU	FISSURE IN ANO	FISSURECTOMY OM 11.09.19	4	4	3	1
12	956271	27	F	HINDU	FISSURE IN ANO	FISSURECTOMY ON 06.07.19	4	0	3	0
13	941846	50	M	MUSLIM	PERIANAL ABSCESS	I & D ON 03.05.19	3	2	4	0
14	957638	42	M	HINDU	FISSURE IN ANO	FISSURECTOMY ON 13.07.19	4	1	4	0
15	947705	67	M	HINDU	FISTULA IN ANO	FISTULECTOMY ON 24.05.19	4	4	4	1
16	943532	32	M	HINDU	PERIANAL ABSCESS	I & D ON 04.05.19	4	1	4	0
17	963476	44	M	HINDU	PERIANAL ABSCESS	I & D ON 14.08.19	3	0	4	0
18	957182	44	M	HINDU	FISTULA IN ANO	FISTULECTOMY ON 11.07.19	4	0	5	0
19	943619	47	M	HINDU	FISTULA IN ANO	FISTULECTOMY ON 04.05.19	4	0	5	0
20	951483	63	F	HINDU	FISSURE IN ANO	FISSURECTOMY ON 14.06.19	4	2	4	0
21	952007	66	F	HINDU	FISSURE IN ANO	FISSURECTOMY ON 14.06.19	4	0	4	0
22	964891	52	F	HINDU	FISSURE IN ANO	FISSURECTOMY ON 23.08.19	4	2	4	0
23	952114	30	M	HINDU	FISTULA IN ANO	FISTULECTOMY ON 17.06.19	4	0	4	1
24	915581	35	M	MUSLIM	FISTULA IN ANO	FISTULECTOMY ON 01.01.19	3	5	4	2
25	949163	55	M	HINDU	FISTULA & FISSURE IN ANO	FISTULECTOMY AND FISSURECTOMY ON 03.06.19	3	5	3	2
26	947718	35	M	HINDU	PERIANAL ABSCESS	I & D ON 24.05.19	3	5	4	1
27	929424	67	M	HINDU	PERIANAL ABSCESS	I & D ON 21.02.19	3	0	5	0
28	928973	75	M	HINDU	PERIANAL ABSCESS	I & D ON 22.02.19	3	2	4	0
29	949957	52	M	HINDU	PERIANAL ABSCESS	I & D ON 05.06.19	4	0	5	0
30	984267	50	M	HINDU	FISTULA IN ANO	FISTULECTOMY ON 22.11.19	4	0	5	0
31	959689	72	M	HINDU	PERIANAL ABSCESS	I & D ON 26.07.19	3	8	4	0
32	952900	48	F	MUSLIM	FISTULA IN ANO	FISTULECTOMY ON 22.06.19	4	2	5	0

CONTROL (SITZ BATH)

Serial No.	IP Number	12	Sex	Religion	Diagnosis	Surgery	Epithelial covering score at the end of 1 month (0-4)	Post-op VAS Pain Score (0-10)	Convenience score (0-5)	Number of DAYS patient missed the procedure IN FIRST WEEK
1	984315	38	M	HINDU	FISTULA IN ANO	FISTULECTOMY ON 21.11.19	4	0	5	2
2	986328	29	F	HINDU	FISSURE IN ANO	FISSURECTOMY ON 03.12.19	3	5	3	2
3	982623	40	M	HINDU	PERIANAL ABSCESS	I & D ON 16.11.19	2	10	2	6
4	976994	21	F	HINDU	FISTULA IN ANO	FISTULECTOMY ON 15.10.19	3	2	3	2
5	974212	57	M	HINDU	FISSURE IN ANO	FISSURECTOMY ON 01.10.19	3	8	2	4
6	965759	36	M	HINDU	FISSURE IN ANO	FISSURECTOMY ON 23.08.19	4	4	2	2
7	964790	28	M	HINDU	PERIANAL ABSCESS	I & D ON 19.08.19	2	5	2	4
8	958999	38	M	HINDU	FISTULA IN ANO	FISTULECTOMY ON 19.07.19	3	2	4	0
9	960561	21	M	HINDU	PERIANAL ABSCESS	I & D ON 27.07.19	3	2	4	0
10	958792	39	M	HINDU	FISTULA IN ANO	FISTULECTOMY ON 19.07.19	3	2	3	2
11	955732	26	M	HINDU	PERIANAL ABSCESS	I & D ON 04.07.19	4	0	4	0
12	954681	22	F	CHRISTIAN	PERIANAL ABSCESS	I & D ON 28.08.19	3	5	3	2
13	950457	65	F	HINDU	FISSURE IN ANO	FISSURECTOMY ON 07.06.19	4	0	3	1
14	948488	58	M	HINDU	FISTULA IN ANO	FISTULECTOMY ON 31.05.19	3	4	2	3
15	949171	40	F	HINDU	FISSURE IN ANO	FISSURECTOMY ON 01.06.19	4	4	3	2
16	947709	38	M	HINDU	FISTULA IN ANO	FISTULECTOMY ON 24.05.19	4	2	4	0
17	943625	25	M	HINDU	PERIANAL ABSCESS	I & D ON 04.05.19	4	2	3	1
18	943367	45	M	HINDU	FISSURE IN ANO	FISSURECTOMY ON 04.05.19	4	5	3	0
19	938405	70	M	HINDU	FISTULA IN ANO	FISTULECTOMY ON 08.04.19	4	2	4	0
20	981047	64	M	HINDU	FISTULA IN ANO	FISTULECTOMY ON 08.11.19	3	5	3	1
21	981170	50	F	HINDU	PERIANAL ABSCESS	I & D ON 11.11.19	3	8	2	4
22	959243	39	F	HINDU	FISSURE IN ANO	FISSURECTOMY ON 23.07.19	4	5	3	1
23	934888	17	F	HINDU	FISTULA IN ANO	FISTULECTOMY ON 22.03.19	3	0	3	1
24	968015	50	M	HINDU	FISTULA IN ANO	FISTULECTOMY ON 07.09.19	3	2	4	0
25	977586	54	M	HINDU	FISSURE IN ANO	FISSURECTOMY ON 17.10.19	3	5	3	1
26	998414	38	M	HINDU	PERIANAL ABSCESS	I & D ON 01.02.20	2	6	3	2
27	1007310	55	M	MUSLIM	PERIANAL ABSCESS	I & D ON 12.08.19	2	5	2	3
28	1001953	62	M	MUSLIM	PERIANAL ABSCESS	I & D ON 19.02.20	3	5	2	3
29	993863	28	F	HINDU	FISSURE IN ANO	FISSURECTOMY ON 08.01.20	3	4	3	2
30	992471	35	F	HINDU	FISSURE IN ANO	FISSURECTOMY ON 02.01.20	4	4	3	4
31	1002259	51	F	HINDU	PERIANAL ABSCESS	I & D ON 19.02.20	2	8	2	5
32	1006046	52	M	HINDU	FISSURE IN ANO	FISSURECTOMY ON 11.03.20	4	2	4	0
33	997920	19	M	HINDU	FISSURE IN ANO	FISSURECTOMY ON 29.01.20	4	5	3	1