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Use of fibrin glue in the treatment of pilonidal sinus disease: a pilot study

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SUMMARY: **Use of fibrin glue in the treatment of pilonidal sinus disease: a pilot study.**

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Background. *Pilonidal sinus (PS) disease of the sacrococcigeal region is an acquired condition resulting from penetration of shed hair shafts through the skin. Different types of operations have been described in the letterature. More recently fibrin glue has been used with succesfull. Aim of this study was to assess the effectiveness of fibrin glue for the treatment of pilonidal sinus.*

Patients and methods. *Eight patients age ranged 21,8 ± 6,5 affected by PS disease of sacrococcigeal region were included in this study. All patients undergoing surgical operation under local anaesthesia. Following administration of 1% methylene blue through the main opening, a small vertical elliptical incision is maked including the entire sinus opening and an excision of PS was performed without entering the sinus cavity, removing a minimal amount of subcutaneous tissue. Afterwards the highly concentrated fibrin glue, containing 1,000 U/ml of thrombin was applied to cover the wound. Post-operative pain, analgesic consumption, duration of hospital stay, failure healing, the rate and time of recurrence, time to healing, time to return to work and post-operative complications were recordered.*

Results. *All patients expressed satisfaction with the procedure. Mean hospital stay was 5.4±2.1 hours. Healing was achieved after 25.8±13.2 days. The post-operative pain mean score was 3.8±2.1 in first day, 2,9±1,8 in third day and 1,3±0,8 in the seventh day. The mean analgesic consumption per week was 5,6±3,2 medications. Mean time to return to work was 5,3±2,1 days.*

Conclusion. *The minimal excision of PS and application of fibrin glue is a non-invasive effective treatment, easy and simple to performe and not associated to recurrences. For these reasons this procedure in our opinion as the first line treatment for pilonidal sinus disease.*

RIASSUNTO: **L'uso della colla di fibrina nel trattamento del sinus pilonidale: studio preliminare.**

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Introduzione. *Il sinus pilonidalis (PS) è una patologia acquisita che deriva dalla inclusione di peli. Sono stati descritti in letteratura differenti approcci terapeutici. Più recentemente è stata utilizzata con successo la colla di fibrina. Lo scopo di questo studio è quello di valutare l'efficacia della colla di fibrina nel trattamento del PS.*

Pazienti e metodi. *Sono stati inclusi in questo studio 8 pazienti, di età media 21,8±6,5 anni, affetti da PS. Tutti i pazienti sono stati sottoposti ad intervento chirurgico in anestesia locale. Dopo l'iniezione di blu di metilene all'1% attraverso l'orifizio cutaneo, è stata praticata un'escissione del PS, senza entrare in cavità, comprendente una piccola pastiglia cutanea ed una minima quantità di tessuto sottocutaneo. Successivamente è stata applicata nella ferita colla di fibrina ad alta concentrazione, contenente 1,000 U/ml di trombina. Sono stati valutati il dolore post-operatorio, il consumo di analgesici, la durata del ricovero, la mancata guarigione, il tempo di guarigione, il tasso e il tempo di comparsa della recidiva, il tempo di ripresa dell'attività lavorativa e le complicanze post-operatorie.*

Risultati. *Tutti i pazienti sono rimasti soddisfatti della procedura. Il ricovero ospedaliero è stato in media di 5,4±2,1 ore, il punteggio medio del dolore post-operatorio è stato 3,8±2,1 in prima giornata, 2,9±1,8 in terza giornata e 1,3±0,8 in settima giornata, il consumo settimanale di analgesici è stato di 5,6±3,2 somministrazioni. Il tempo di ripresa dell'attività lavorativa è stato in media di 5,3±2,1 giorni.*

Conclusioni. *L'escissione del PS, comprendente una minima quota di tessuto sottocutaneo, e l'applicazione di colla di fibrina è un trattamento non invasivo, di facile e semplice esecuzione e risolutivo. Per queste ragioni tale procedura può essere considerata il trattamento di prima scelta del PS.*

KEY WORDS: Pilonidal sinus - Fibrin glue.
Sinus pilonidalis - Colla di fibrina.

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Introduction

Pilonidal sinus (PS) disease is a common condition affecting tipically young male patients after puberty. PS has widely been accepted as an acquired condition that results from the penetration of shed hair shafts through the skin (1).

Management of this disease remains controversial. Many different types of operations have been described in the literature: brushing or phenolization of the track, simple incision and drainage, laying open, marsupialization, excision and open granulation, elliptical, medial or paramedial excision and primary closure, rhomboid excision and the flap procedure.

An ideal treatment should be simple, should require short or no hospital stay, should have a low recurrence rate, should be associated with minimal pain and wound care, to decrease time off work (2), and should be low cost with a good aesthetic results (3).

Recently fibrin glue has been used for the treatment of PS with encouraging results. The advantage of using fibrin glue is that healing of the track can be achieved without excision of a large amount of tissue. This study was designed to investigate the role of fibrin tissue glue as a minimal potential invasive treatment for PS disease.

Patients and methods

This study includes 8 male patients who underwent surgery for PS disease. Patients gave a written, informed consent and the local ethical committee and the departmental internal review board approved the study. The patients age was 21,8±6,5 years (mean ± standard deviation), and a family history was present in two of them. Sinuses with purulent discharge were considered acute, sinuses that had serous leakage inactive disease previously infected were considered chronic. The mean period of time during patients had symptoms was 9,5±13,8 months. Five sinuses were acute, the mean number of sinuses opening was 2±1. The direction of sinuses was cephalad for five patients, caudate for two and both for one patient. The exclusion criteria in this study were: patients with a very large cavity and with acute abscess; small inactive PS disease previously not infected; number of the tracts more than three; sinus extending lateral to the anal cleft and orifice near to the anus; recurrent disease.

All patient received a single intravenous dose of ceftazidine and metronidazole and were operated on under local anaesthesia. The natal cleft was shaved the day before the surgery. The patients were placed in prone jack-knife position on the operating table with the legs slightly abduced and with a pillow under the pelvis to elevate it. The buttocks strapped apart by adhesive tapes on the table. Local anaesthesia is achieved by infiltration of about 20 ml of 0,5 bupivacaine around the PS.

Following administration of 1% methylene blue through the main opening, a small vertical elliptical incision is maked including the entire sinus opening, and an excision of PS was performed without entering the sinus cavity, removing a minimal amount of subcutaneous tissue. When are present two or more fistulous orifices, some small and separated elliptical incisions were performed. The highly concentrated fibrin glue (Tissucol®, Baxter, Vienna), containing 1,000 U/ml of thrombin was used. The thrombin and activating factors, each in a separate container, were then aspired into a double-armed syringe attached to a soft triple lumen catheter; the third one for the air was not used in the study. After that the stretched buttocks are released, the fibrin glue was injected simultaneously slowly with drawing the catheter. Gause is applied to cover the wound to prevent water coming into contact with the fibrin glue.

The duration of hospital stay, the post-operative pain, the analgesic consumption, the failure healing, the rate and time of recurrence, the healing time, time to return to work and the post-operative complications (infection, oedema) were recordered. The term "recurrence" was used when symptoms of the disease reappeared after an interval following complete wound healing. Any wound that did not heal despite aggressive wound care was accepted as a "healing failure" rather than "disease recurrence". "Healing time" was defined as the period from the date of the operation to the date when the wound was completely closed. The time of incapacity to work was defined as the time from the date of surgery to the date on which the patient returned to normal activities including employment and leisure activities. A visual analogic scale from 0 to 10 was used to evaluate pain where 0 corrisponded to no pain and 10 to the worse conceivable pain. The assessment of pain was made 1st ,2nd and 7th day after operation. The analgesic consumption was evaluated up to the seventh day. All patients are reviewed in the ambulatory after two, five e seven days and then weekly until the wound had healed and there after every four months for one year.

It was recommended that they had to bath at least five times a week and they had to depilate on the operation site monthly using a depilatory cream starting after healing. We encouraged the patients to return to their normal activity as soon as possible because it was reported that the wounds healed more quickly in those patients who resumed their normal routine before the closure of the wound (4). All patients were advised thoroughly to contact our out-clinic if any problems would appear from or in the operated region during the appointments after fully healed.

Results

All patients were discharged on the same day after surgery. The mean lenght of hospital stay was 5,4±2,1 hours. The amount of fibrin glue was 1,9±0,6 ml/L. The medication number in hospital were 5,2±3,1.

Wound infection or failure of healing was not observed in any patients. Healing was achieved after 25,8±13,2 day. Only a patient had a breakdown of the fibrin glue at the outpatient visit and was managed with a second application of fibrin glue.

The postoperative pain mean score was 3,8±2,1 in first day, 2,9±1,8 in third day and 1,3±0,8 in the seventh day. The mean analgesic consumption per week was 5,6±3,2 medications. Time to return to work was 5,3±2,1 days. All patients during follow-up practised at least five showers a week and they used monthly a depilatory cream. There has been no recurrence in any of the patients at follow-up.

All patients expressed satisfaction with the procedure.

Conclusion

There are two conflictual theories of pathogenesis. They have both implications for the extent of surgical resection thought necessary to achieve a cure. From the end of the 1st century to the beginning of the 20th century, the disease was studied on an embryologic basis by many authors who considered it of congenital origin (5). On the basis of this hypotesis thus the radical removal of all tissue overlying the sacrum in order to remove all embryologic remnants should not be regarded as essential to treatment (6). Patey and Scarf, soon after the end of World War II, hypothesized that the disease was acquired by the penetration of hair into subcutaneous tissue, with consequent granulomatous reaction (7). They introduced this concept based on the high incidence of recurrence after complete excision of all tissue overlying the sacrum and on the occurrence of the disease in other locations of the body (7). On the basis of this theory, it has been proposed the incision and curettage as method of choise to treat the disease (5). This operation consists of exeresis of the granulomatous tissue that contains the hair responsible for the above-mentioned reaction. According to Karydakis, three main factors play a part in the hair insertion process: 1) the invader, consisting of loose hair, 2) some force, which causes hair insertion, and 3) the vulnerability of the skin (8). If these three main factors occur, then hair insertion and PS results. Thus, for treatment and prevention of PS, these causative factors must be eliminated (8).

With the recognition that pilonidal disease is an acquired lesion rather than a congenital abnormality, this treatment has progressively become less invasive and less aggressive (1). Armstrong and Barcia training a conservative treatment, no excisional with meticulous hair control by natal cleft shaving, improved perineal hygiene, and limited lateral incision have had good results (9). Limited excision of the fistulous tract and their wounds were left opened for secondary intention healing and represents one of the best therapeutic options (10,11). The result of this method is comparable with the more aggressive frequently used a large excisional and a primary closure and it has the advantage of having a shorter convalescence and better patient satisfaction although time of healing is more longer (10).

Recently fibrin glue has been used extensively by surgeons for the treatment of various conditions (12). It acts by supporting angiogenesis, fibroblast proliferation and collagen production. Trying to reduce the healing time and with the purpose to practise procedures minimally invasive the fibrin glue was used to treat the PS. The fibrin glue has been used for the first time after wide excision of sinus complex (13). Then Greenberg et al. in 2004 combines a curved skin incision and elevation of thick skin flap, complete excision of the sinus and all its extensions, approximation of the flap back to its original place, and injection of 2-4 ml of fibrin glue through the original PS opening to hill the dead space under the skin flap (14). Seleem and Al-Hashemy in 2005 used fibrin glue after excision a minimal amount of skin and subcutaneous tissue (15), while Lund and Leveson after excision of the epithelium of the sinus (16).

The minimal excision with tension free and application of fibrin glue that we use is non invasive treatment and it result easy and simple to perform and it is not associated to recurrent disease. It can be performed under local anaesthesia, it no require many medications and long hospital stay, minimal post-operative disability and the operation may be performed by surgeons who are less experienced. It has a good aesthetic result without any disfigured scars saving the natural and deep shape anal cleft. The prophylaxis of recurrent disease, as there are the previously anatomic-clinical conditions, has to be granted to a personal local hygiene with frequent showers so that the skin soaking induced by bacterium superposition can allow the penetration of shed hair shafts in the fragile skin plane of the anal cleft. Besides the depilation with cream or laser (17) seems to be very important; infact the new growth and the aumont of hair are important factors to cause the recurrence desease because there is not PS without hair (18). In conclusion this procedure is suggested as the first-line treatment of patients with any type of PS. Further randomized prospective studies should be conducted to value the detailed role of fibrin glue application for treatment of PS.

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