Pilonidal Sinus Wounds: Secondary Intention Healing with a plant-based wound therapeutic

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SUMMARY

Objective: To evaluate the effectiveness of a plant-derived wound dressing, a mixture of Hypericum and neem oil (ONE), in secondary intention healing of Pilonidal Sinus Wounds.
Method:
21 consecutive patients with a pilonidal sinus wound following a surgical excision were analysed retrospectively. Time to healing, time to return to work, recurrence rate, ease of handling, pain and other complications were evaluated.
Results: The 21 patients (15 male, 6 female) with a mean age of 26 years (20 - 36) had pilonidal sinus wounds with a mean wound length of 4.6cm (2.5cm - 10cm), a mean wound width of 2.4cm (0.5cm - 5cm), resulting in a mean wound size of 9.4cm2 (1.0cm2 - 23.7cm2), calculated with the ellipse method. The wounds had an average depth of 2.8cm (1.2cm - 7cm). The average time to complete healing by secondary intention was 52 days (35 days - 119 days). The application of ONE led to wound closure in all wounds. The average time to return to work was 15 days. Dressing change was easy and without pain and there were no infections or other complications. After an average of 125 days (0 days - 264 days) after wound closure the recurrence rate is 0%.
Conclusion: The results of this retrospective non-controlled analysis suggests that the plant-derived wound spray ONE is an easy to handle, clinically efficient and cost-effective non-touch therapy for the secondary intention healing of small to large pilonidal sinus wounds. Further studies are required to document the effectiveness of this wound therapeutic in a controlled fashion.

DECLARATION OF INTERESTS

The authors declare that there is no conflict of interest.

LIMITATIONS

Even though the sample size represents the typical age and gender pattern described in literature the number is small. The data is analyzed retrospectively and indirectly compared with published data. Even though the characteristics of the wounds in this study are similar to those reported in other published trials the interpretation is challenging. Despite this, the results compare favorably with those from literature.

KEYWORDS

Pilonidal Sinus; secondary intention healing; wound therapeutic; Neem oil; Hypericum oil

INTRODUCTION

Pilonidal disease is a chronic infection of the skin in the region of the buttock crease. It is thought that the condition results from a reaction to hairs embedded in the skin, commonly occurring in the cleft between the buttocks. The disease is 2.2 times more common in men than women (Sondenaa et al, 1995) and frequently occurs between puberty and age 40, with a peak at 19 years of age in females and 22 year in males (Clothier and Haywood, 1984). Familial disposition (38%), local trauma (34%), overweight (37%) and obesity (13%) seem to be contributing factors to pilonidal disease (Sondenaa et al, 1995). Even though pilonidal sinus disease was first described in 1847 (Anderson, 1847), the origin of pilonidal sinus disease is not yet fully understood. Two theories, the 'acquired theory' and the 'congenital theory' have emerged as possible explanations (Bascom, 1980; Bascom, 1983; Chamberlain and Vawter, 1974).

Many different surgical and non-surgical treatment techniques have been advocated and no technique has evolved as the ideal or widely accepted method. Surgical procedures vary from unroofing the sinuses to excision and possible closure with flaps (Khalid, 2001) with time to wound healing, surgical site infection rates, recurrence rates, time to return to work, patient

comfort and costs being the main parameters that influence the surgeon's decision which technique to favor. Excision with primary closure or healing by secondary intention is the most commonly performed surgical procedure (Chiedozi et al, 2002).

Time to wound healing for secondary intention healing following an excision can range from 64 days to 91 days, while for excision with primary closure average values of 15 to 27 days are reported (Al-Hassan, 1990; Gencosmanoglu, 2005; Christensen, 1985). An intervention review done by the Cochrane Collaboration concluded that the data for time to wound healing of all available RCT's are too heterogenic to perform relevant statistical analysis (Al-Khamis et al, 2011). Nasr and Sigmund performed an interesting retrospective review of all adolescents patients with pilonidal disease treated from July 1969 to December 2003 by the same surgeon (Nasr et al, 2009). During this time span, 90 adolescents had a pilonidal excision with healing by seconary intention. The mean healing time of these patients was 75 days, which is in line with the data from Al-Hassan, Gencosmanoglu and Christensen. However, due to the aerobic organisms regularly found in the natal cleft, secondary intention healing after wide excision can take longer and result in healing rates of up to 6 months (Marks et al, 1987; Harris et al., 2012).

The rate of surgical site infection after pilonidal surgery is not statistically different between open healing versus primary closure with average values found in literature ranging from 9% to 22% for open healing (Al-Khamis et al, 2011; McCallum I et al, 2008).

Recurrence rate and time to return to work are important parameters as they are directly associated with patient comfort and cost. The recurrence rate for pilonidal sinus wounds healed by secondary intention is 3.6% if the follow-up period is <1 year and 6.9% if the follow-up period is >1 year (McCallum I et al, 2008; Al-Khamis et al, 2011). Ahmed et al reported recurrence rates of 22% with a mean time to recurrence of 195 (range 30-390) days for adolescents. The recurrence rate is significantly higher compared to other studies because postoperative infections were counted as recurrence since they did not heal unless treated as a recurrence (Nasr et al, 2009). Open healing of pilonidal sinus is associated with a 58% lower risk of recurrence than primary closure (Al-Khamis et al ; McCallum I et al, 2008). Patients undergoing excision with open healing take longer to return to work (17 to 28 days) than those having closed operations regardless of closure method (11 to 15 days) (Al-Khamis et al, 2011; Al-Hassan, 1990; Sondenaa et al, 1992; Füzün et al, 1994).

Pain is typically reported as a post-surgical symptom. There does not seem to be a statistically significant difference between the different surgical techniques in regard to post-surgical pain (McCallum I et al, 2008). We have observed in our daily clinical practice that patients treated with simple wet gauzes or hydrofibre as primary dressing report that they suffer from dressing change related pain as the dressings are adhering to the wound.

Wound healing rates found in literature for open healing are 92% , not statistically significantly different from wound healing rates for primary closure, which is 100% (Al-Khamis et al, 2011).

Many different techniques and dressings for the management of wounds left open for secondary intention healing are available but there is no evidence that one dressing is superior to another in terms of healing rate (Berry et al, 1996). Taking all factors mentioned above into account an ideal dressing should have following attributes: it should be easy to apply, enable a painless dressing change, have antimicrobial properties, promote granulation and manage the exudate.

In 2011, "1 PRIMARY WOUND DRESSING®" (ONE; Phytoceuticals AG), a new plant-derived wound therapeutic was introduced to the Swiss market. ONE consists of a specially formulated mixture of Hypericum oil (Hypericum perforatum) and Neem oil (Azadirachta indica). Designed as a spray, ONE offers a simple mode of application. ONE creates a moist wound environment and the oil layer prevents the secondary dressing from adhering to the wound. Furthermore ONE has an anti-microbial effect and promotes the regeneration of the epidermis. The simple mode of application combined with the broad mode of action qualified the product to be used on pilonidal sinus wounds.

The objective of this retrospective study was to evaluate the effectiveness of ONE in the treatment of pilonidal sinus wounds by secondary intention healing.

METHODS

21 consecutive patients with a pilonidal sinus wound following a surgical excision were analysed retrospectively. 10 patients were treated at the Department Surgery of the Schwyz Cantonal Hospital, Schwyz, Switzerland, 7 patients at the Department of Surgery of the Lucerne Cantonal Hospital, Wolhusen, Switzerland and 4 patients at the Department of Surgery of the Regional Hospital Surselva, Ilanz, Switzerland from May 2012 to January 2013.

The wounds were treated with ONE. The spray was applied daily on the wound and periwound skin after being cleaned by irrigation. The wound and periwound skin was then covered with a simple secondary dressing (non-woven gauze or absorbent dressing), without any active compound. The choice of the secondary dressing was based on the amount of wound exudate. Debridement and cleansing of the wound was only performed when necessary. Fibrinous tissue was not removed.

Treatment was continued until secondary epithelialisation. All the patients were seen at least every two weeks by a wound-care specialist. Dressing change in between the visits at the clinic was performed either by a family member, the homecare organization or the patient himself. Before starting the ONE treatment and at every clinical visit, the wounds were photographed together with a ruler, the wound depth measured and the wound size was determined with the ellipse method. At each follow-up visit, pain (assessed by open question), clinical signs of infections, as well as any side effects, were recorded.

Wound healing was defined as complete closure of the wound by secondary epithelialisation. Time to healing was defined as the time between the first application of ONE and complete wound closure. Time to return to work was defined as the time between the day of the excision and the day of returning to work.

Informed consent was obtained from all patients that their data could be submitted for publication.

RESULTS

Over the study period, 21 consecutive patients (15 male, 6 female) with a pilonidal sinus wound following a surgical excision were treated with ONE. 6 of the 21 patients (28%) have experienced a pilonidal sinus wound episode before. All patient records included the required information except for the data on pain in 5 cases and data for time to return to work in 3 cases.

The patients' mean age was 26 ± 5.6 years (range 20–36 years). Secondary diagnoses included rheumatism (n=1). The mean wound length of the pilonidal sinus wounds after the excision was 4.6±2.2cm (range 2.5–10cm), the mean wound width was 2.5±1.0cm (range 0.5–5cm), resulting in a mean wound size of 9.4±6.1cm^2 (range 1.0cm^2 - 23.7cm^2), calculated with the ellipse method. The wounds had an average depth of 2.8±1.4cm (range 1.2cm - 7.0cm).

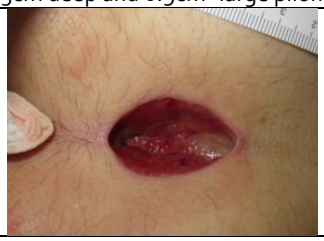
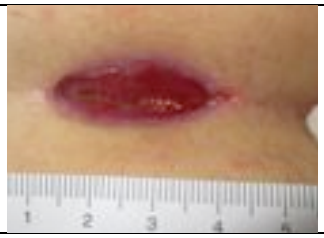
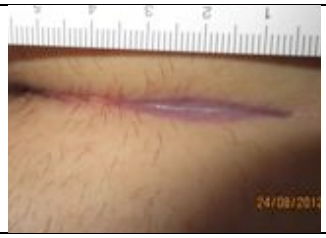
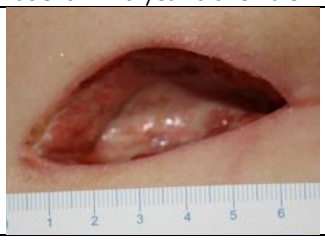
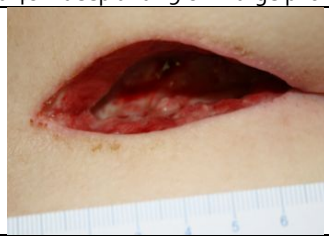
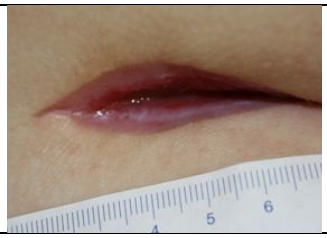
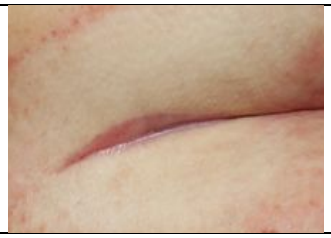
All 21 pilonidal sinus wounds completely healed by secondary intention, without any further surgical or other intervention (table 1; figure 1). The mean Time to healing until total re-epithelialisation of the wounds was 52±22 days (range 35–119 days; table 1). The mean time to return to work was 15±9 days (range 7–35 days; table 1). The mean pain experienced by 16 patients at the beginning of the treatment was 2/10 and declined to 0/10 after 10 days of treatment (table 1). All patients were under pain medication for the first 7 days after the surgery. The patients did not experience pain during the rest of the treatment and in particular during the dressing changes. No wound exhibited clinical evidence of superficial or deep infection. None of the patients had received a systemic antibiotic treatment. None of the patients showed signs of allergic reactions and no other side effects were observed. Review of clinical photographs of the healed wounds showed a cosmetically satisfying outcome in all patients. By the time of submitting this paper for publication (a mean duration of 125 days (range 0-264 days) the recurrence rate was 0% (table 1). Dressing changes in between the visits at the clinic were performed by the patient himself in 5 cases, by a family member or relative in 14 cases and by a home care organziation in 2 cases.

Table 1: Case reports of the 21 patients treated with ONE

Patient no.	Sex	Age	Wound size		Pain		Time to healing (days)	Time to return to work (days)	Recurrence since wound closure	
			Length, width, depth (cm)	Area (cm^2)	At Treatment start	After 10 days of treatment			y/n	Time since wound closure (days)
1	M	21	3.5 - 2.5 - 2.5	6.9	na	na	52	14	n	201
2	W	31	2.5 - 1.5 - 1.2	3.0	na	na	35	10	n	219
3	M	25	2.6 - 2.5 - 2.5	5.1	0/10	0/10	39	14	n	156
4	M	22	4.5 -3.0 - 2.5	10.7	na	na	43	44[1]	n	154
5	M	27	8.0 - 2.0 - 3.5	12.6	0/10	0/10	48	7	n	126
6	M	29	3.0 - 1.5 - 1.5	3.6	3/10	0/10	41	7	n	114
7	M	24	2.5 - 0.5 - 3.0	1.0	0/10	0/10	68	7	n	40
8	M	26	5.0 - 3.0 - 3.0	11.9	1/10	0/10	52	35	n	98
9	M	30	10 - 3.0 - 3.0	23.7	1/10	0/10	119	28	n	0
10	M	34	5.5 - 1.5 - 1.5	5.5	3/10	0/10	35	30[1]	n	19
11	W	20	6.0 - 4.0 - 4.0	19.0	1/10	0/10	57	10	n	264
12	M	36	6.0 - 3.0 - 3.5	14.2	2/10	0/10	62	21	n	231
13	W	21	5.0 - 5.0 - 7.0	19.8	1/10	0/10	92	14	n	147
14	M	32	4.5 - 2.0 - 3.0	7.1	0/10	0/10	45	10	n	155
15	M	20	7.0 - 2.3 - 1.5	12.7	2/10	0/10	70	20	n	123
16	M	20	4.0 - 2.0 - 1.0	6.3	na	na	30	7	n	96
17	W	29	4.0 - 1.5 - 1.0	4.7	na	na	27	21	n	113
18	W	19	3.5 - 2.5 - 4.0	6.9	2/10	2/10	62	14	n	67
19	M	30	4.5 - 3.5 - 5.0	12.4	4/10	0/10	45	45[1]	n	116
20	M	15	3.0 - 2.5 - 2.5	5.9	1/10	0/10	22	7	n	120
21	W	26	3.0 - 1.5 - 2.5	3.6	2/10	0/10	65	65[1]	n	167

[1] These cases were excluded from the calculation of average value since the patients were not allowed to return to work prior to having a completely healed wound due to work related regulations.

Figure 1: Case reports of the 21 patients treated with ONE

Patient 1: 21-year-old male with a 2.5cm deep and 6.9cm² large pilonidal sinus wound			
			
Day 3 post surgery: healthy wound with some fibrin coating	Day 9: Clean wound, visible induction of granulation tissue growth	Day 21: Rapid filling-up of the wound with granulation tissue and contraction of the wound	Day 52: Complete wound closure with a good cosmetic outcome
Patient 11: 20-year-old female with a 4cm deep and 19 cm² large pilonidal sinus wound			
			
Day 3 post surgery: healthy wound with some fibrin coating	Day 14: Clean wound, visible induction of granulation tissue growth	Day 28: Rapid filling-up of the wound with granulation tissue and contraction of the wound, partial re-epithelisation	Day 57: Complete wound closure with a good cosmetic outcome

DISCUSSION

Excision and healing by secondary intention is a common procedure for the treatment of the pilonidal disease (Chiedozi et al, 2002). Alternative procedures vary from unroofing the sinuses to excision and primary closure or possible closure with flaps (Khalid, 2001). Time to wound healing, recurrence rate, infection rate, patient comfort and costs are the main parameters that influence the surgeon's decision which procedure to favor.

The present retrospective non-controlled analysis suggests that a plant-derived wound dressing (ONE), is a promising therapy to support the secondary healing process of pilonidal sinus wounds. Time to wound healing commonly seen for pilonidal sinus wounds healing by secondary intention can range from 64 days to 91 days (Al-Hassan, 1990; Gencosmanoglu, 2005; Christensen, 1985) and can, due to the aerobic organisms regularly found in the natal cleft, result in healing rates of up to 6 months (Marks et al, 1987; Harris et al., 2012). The average time to wound healing for the 21 patients treated with ONE was 52 days (table 2), which appears superior to healing rates found in literature for secondary healing. This is a clear indication for the impressive granulation effect resulting from the application of ONE which led to a progressive filling up even of large skin defects.

This granulation effect can be explained by the combination of the antimicrobial activity of the fatty acids contained in ONE (Desbois, 2010), the balanced moist environment obtained by the semi-occlusive layer ONE creates (Sharman, 2003) and the fact that the oil layer prevents secondary dressings from adhering to the wound (Bell, 2010). Thereby, cell proliferation is activated and despite the moist environment, the bacterial load remains under control. In addition, damage of the granulation tissue and regenerating epithelium during dressing change is prevented. This effect was also observed in other case series performed with ONE in open granulating wounds (Wehrmann et al. 2011; Läuchli et al., 2012; Hunziker et al., 2012). This result is interesting from a cost perspective as large pilonidal sinus wounds are often treated with Negative Pressure Wound Therapy (NPWT). As demonstrated by Läuchli, the treatment of open granulating wounds with ONE can offer significant cost benefits if compared to NPWT (Läuchli et al., 2012) on open granulating wounds.

Table 2: Comparing the main healing parameters for open healing (literature based and treatment with ONE) and primary closure (literature based) for the treatment of pilonidal sinus disease

	Open healing (literature based)	Primary closure (literature based)	Open healing (treated with ONE)
Time to wound healing	64 - 91 days	15 - 27 days	52 days
Rate of surgical site infection	7 - 22%		0%
Recurrence rate	3.6%[1] and 6.9%[2]	16.4%[2]	0%[3]
Time to return to work	17 - 28 days	11 - 15 days	15 days
Wound healing rate	92%	100%	100%

[1] Follow-up period < 1 year

[2] Follow-up period > 1 year

[3] Average follow-up period of 125 days

Besides time to wound healing, recurrence rate and time to return to work are important parameters as they are directly associated with patient comfort and cost. The recurrence rate for pilonidal sinus wounds healed by secondary intention in the literature is 3.6% if the follow-up period is <1 year and 6.9% if the follow-up period is >1 year (McCallum I et al, 2008). By the time of submission of this publication (an average of 125 days (0 days - 264 days after wound closure) the recurrence rate is 0% which is below the expected recurrence rate of 3.6%. According to literature, patients undergoing excision with open healing take 17 to 28 days to return to work (Al-Hassan, 1990; Sondenaa et al, 1992; Füzün et al, 1994). Patients treated with ONE were able to return to work on average 15 days (7 days - 35 days) after the surgery.

Secondary intention healing of pilonidal sinus wounds is associated with surgical site infection rates of 9% to 22% (McCallum I et al, 2008). In our case series we have not observed any clinical evidence of superficial or deep infection. No patient received a systemic antibiotic treatment. This positive result may be partly explained by the antimicrobial activity of the fatty acids contained in ONE (Desbois, 2010).

Pain was not an important factor during the first week after the surgery. 16 patients indicated an average pain sensation of 2/10 at day 3 post surgery. This is due to the fact that all patients receive pain medication during the first week after the surgery. We have observed in our daily clinical practice that patients treated with simple wet gauzes or hydrofibre as primary dressing report that they suffer from dressing change related pain as the dressings are adhering to the wound. It was therefore interesting to observe that the 16 patients did not experience any pain after stopping the intake of pain medication and in particular during dressing changes. This effect may be explained due to the oil layer, which prevents the secondary dressings from adhering to the wound (Bell, 2010). This leads to a reduction in pain during dressing change.

The application of ONE enables a very simple and rapid dressing change since the form of application is a spray. Dressing changes in between the visits at the clinic were performed by the patient himself in 5 cases, by a family member or relative in 14 cases and by a home care organization in 2 cases. This offers additional cost benefits, especially for the treatment of large skin defects where NPWT is applied.

Taking all observed factors together the application of ONE clearly has the potential to offer clinical and economic benefits, making the secondary healing of pilonidal sinus wounds more effective.

CONCLUSION

The results of this retrospective non-controlled analysis suggests that the plant-based wound therapeutic ONE offers a clinically efficient and potentially cost effective therapy for the secondary intention healing of pilonidal sinus wounds following an excision. Further studies with a larger number of patients are required to document the effectiveness of ONE in a controlled fashion.

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