



Research Article

AN OPEN LABEL, RANDOMIZED, COMPARATIVE, PARALLEL GROUP, SINGLE CENTER STUDY TO EVALUATE SAFETY AND EFFICACY OF ANO SPRAY IN A COMPARISON WITH BETADINE SOLUTION APPLICATION IN ACUTE PERINEUM WOUNDS

Porwal Ashwin^{1*}, Gandhi Paresh², Deepak Kulkarni²

*¹Consultant colorectal Surgeon, ²General surgeon, Healing Hands clinic, 4th floor, millennium star extension, Above KFC, adjacent to ruby hall clinic, Dhole Patil road, Pune.

Article info

Article History:

Received: 25-02-2018

Accepted: 24-03-2018

KEYWORDS: Perineum wound, Visual analogue scale (VAS).

ABSTRACT

Perineal wound are common post-surgical treatment of perianal diseases and in disease near perianal region. In current existing treatment modalities there is no significant number of patients who get relief from perineal wound. We have conducted an open label, randomized, parallel group and single center study to observe safety and efficacy of Ano Spray. Total 30 patients were randomized on Ano spray group and betadine solution group (1:1 ratio). All the patients were advised to apply Ano spray and betadine solution twice daily for 4 weeks. All patients visited center on Day 0, Week 1, 2, 3 and 4. Patient's quality of life on PAC-QOL & pain was assessed on VAS score on each visit. Local examination was done at each visit for discharge, itching and healing progress. In Ano spray patient's group wound is significantly healed in lesser time in comparison with Betadine solution group. In both group VAS score for pain was significantly ($p < 0.05$) improved from baseline Day 0 to Week 4 and significantly improvement observed in Ano spray group. At the end of the study (Week 4), significant ($P < 0.05$) results were observed in Ano Spray group than Betadine solution group in itching and discharge associated with wound. Excellent overall efficacy and tolerability was observed in patients of both the groups. No adverse event or adverse drug reaction was noted in any patient of both the groups. Study result shows Ano Spray is safe and superior to Betadine Solution in perineum wound healing.

*Address for correspondence

Dr. Porwal Ashwin*

Consultant colorectal Surgeon,
Healing Hands clinic,
4th floor, millennium star
extension, Above KFC, adjacent to
ruby hall clinic, Dhole Patil road,
Pune.

Contact: +91 9822347770

Email:

drashwinporwal@healinghandsclinic.co.in

INTRODUCTION

The perineum includes the region between the pubic symphysis and the coccyx and is probably derived from the Greek words "peri+inan" meaning to "empty out".^[1] All the diseases near perineum region may come with irritation, inflammation and pain. They may turned into wounds with draining blood, pus, purulent non purulent discharge. Even after surgical treatment possibility of post-operative wound can't be denied. These wounds result in significant morbidity requiring prolonged hospital stay, hospital readmission, home-nursing wound care needs; all involving significant medical costs. For the patient, these wounds are painful, malodorous lesions requiring constant care and adversely affecting the quality of life. [2]In current

existing treatment modalities there is no significant number of patients get relief. The main objective of this study is to access safety and efficacy of Ano Spray, a pure herbal formulation in comparison with Betadine solution application in patients who have perineal wounds.

Materials and methods

In this open label, randomized, parallel group and single center study total 30 patients were randomized randomly on active group (Ano spray) and comparative group (betadine Solution) (1:1 ratio). Study was conducted in healing hands clinic Pune, from January 2017 to November 2017. Ano spray is an Ayurvedic polyherbal formulation in form of spray. The formulation of Ano spray

comprises *Daruharidra* (Indian barberry) 2-10%, *Lodh* (*Symplocos racemosa*) 1-8%, *Mochras* (Gum of silk Cotton Tree) 1-6%, *Teel Tail* (*Sesamum indicum*) 50-80%, *Kokam Tail* (*Garcinia indica*) 5-15%, *Kapur* (*Camphora*) 2-6% and *Menthol* (*Mentha sylvestries*) 1-4%.

We enrolled patients who developed perineal wounds after disease near perianal region (Anal fissure, anal fistula) and after surgical treatments (fistulectomy and sphincterotomy). Patient age between 18- 60 yrs. Patient having anal abscess, high blind fistula track anal cancer were excluded. All patients visited to study center on week 1, 2, 3 and 4. Patient's quality of life was assessed by Patient Assessment of Constipation-Quality of Life Questionnaire (PAC-QOL). Pain was assessed on Visual Analogue Scale (VAS) on each visit. Local examination was done on each visit for discharge, itching, assessment for hyper granulation & healing progress. Data were managed on an excel spreadsheet. All analyses were performed using SPSS version 21.0 software. Data describing quantitative measures were expressed as mean (SD). Comparison of variables representing categorical data was performed using "Chi-square test" Group means of dependent sample were compared by means of ANOVA (repeated-measures design, generalized linear model procedure) or Wilcoxon sign rank test. Corresponding contrasts were tested using t-test for dependent samples and nonparametric test like "Wilcoxon Sign Rank" Test. p value <0.05 was considered to be statistically significant. All the patients were advised to apply Ano spray or betadine solution twice daily for 4 weeks.

Results and discussion

Total 30 patients enrolled and randomized randomly on Ano Spray and betadine solution (1:1 ratio). An analysis done for 30 patients out of that, 16, 53.33% (n, %) were men while 14, 46.67% (n, %) were women and the mean age was 48.7 ± 13.06 years. Ano spray group patient's wound healed significantly in lesser time i.e. 3.4 weeks (mean) than comparative group i.e. 7.6 weeks (mean). There was no significant change in vital signs like pulse rate, body temperature, respiratory rate, and the blood pressure in both groups.

In Ano spray 60% patients wound was completely healed and in Betadine solution group 33.33% patients wound was completely healed, same is reflected in Table 1. It also shows in Ano spray patient's group wound is significantly healed in lesser time 4.1 weeks (mean) in comparison with Betadine group. In both group VAS score for pain was significantly ($p < 0.05$) improved from baseline Day 0 to Week 4 and significant improvement observed in Ano spray group (Table 2). Total score of PAC-QOL and scores for each of the subscales (worries and concerns, physical discomfort, psychosocial discomfort, and satisfaction) significantly improved in Ano spray group ($p < 0.05$) from baseline Day 0 to Week 4, as shown in (Table 3).

At the end of the study (week 4), significantly ($P < 0.05$) results were observed in Ano spray group than Betadine solution in itching and discharge associated with wound. Excellent overall efficacy and tolerability was observed in patients of both the groups. No adverse event or adverse drug reaction was noted in any patients of both the groups.

Table 1: Wound Healing at each visits between the groups

Study Visits	Wound status	Ano spray (n)	%	Betadine Solution (n)	%
Day 0	Present	15	100.00	15	100.00
Week 1	Same	14	93.33	15	100.00
	Slight wound size decreased	1	6.67	0	0.00
Week 2	Same	8	53.33	11	73.33
	Slight wound size decreased	6	40.00	4	26.67
	More wound size Decreased	1	6.67	0	0.00
Week 3	Same	3	20.00	5	33.33
	Slight wound size decreased	2	13.33	4	26.67
	More wound size Decreased	9	60.00	5	33.33
	Completely Healed	1	6.67	0	0.00
Week 4	Same	1	6.67	3	20.00
	Slight wound size decreased	2	13.33	2	13.33
	More wound size Decreased	5	33.33	3	20.00
	Completely Healed	8	53.33	5	33.33

Table 2: Pain on VAS scale

	Ano Spray (n=15)	Betadine Solution (n=15)
Study Visits	Mean±SD	Mean±SD
Baseline (day 0)	8.30±0.48	8.27±0.46
Week 1	6.60±0.52	6.87±0.83
Week 2	4.60±0.7	5.07±1.22
Week 3	3.80±0.42	4.13±0.74
Week 4	2.40±0.84	3.13±0.83
*p<0.05, significant by Wilcoxon signed rank as compared between the groups		

Table 3: Quality of life during study

Study Visits	PAC- QOL	Worries and concern	Physical discomfort	Psychosocial discomfort	Satisfaction
(Ano Spray)	Mean±SD	Mean±SD	Mean±SD	Mean±SD	Mean±SD
Week 1 (n=15)	2.61±0.71	2.47±0.91	2.78±1.10	2.24±1.13	1.42±0.78
Week 2 (n=15)	1.81±0.68	1.45±1.25	1.15±1.09	1.98±1.15	0.79±0.51
Week 3 (n=15)	0.78±0.61	0.86±0.90	0.82±0.89	0.94±0.87	- 0.14±0.71
Week 4 (n=15)	0.51±0.58	0.49±0.77	0.78±1.10	0.78±0.71	- 0.64±0.68
(Betadine Solution)	Mean±SD	Mean±SD	Mean±SD	Mean±SD	Mean±SD
Week 1 (n=15)	2.87±0.89	2.61±0.77	2.81±1.25	2.26±1.13	1.52±0.79
Week 2 (n=15)	1.98±0.84	1.59±1.35	1.45±1.39	1.98±1.15	0.81±0.58
Week 3 (n=15)	0.98±0.81	0.91±0.90	0.89±0.89	0.94±0.87	0.84±0.81
Week 4 (n=15)	0.87±0.69	0.89±0.81	0.78±1.10	0.98±0.91	0.78±0.69
*p<0.05, significant by student 't' test as compared to baseline to Week 4					

Management of perineal wounds can be very frustrating as these invariably get contaminated from the ano-genital tracts.^[2] The initial management of nonseptic wound dehiscence is typically conservative. In general, this is comprised of wound care with dressing changes.^[3] In the Indian context, the formal descriptions of wound care have been vividly elaborated in the three great treatises (*Brahatrayi*) of Ayurveda viz. *Charaka Samhita*, *Sushruta Samhita* and *Astanga Sangraha*. These documents not only describe *Vrana* (various types of wounds) but they also present their systematic classification along with their management including various systemic and local drugs and preparations. *Sushruta*, the father of Indian surgery in 1000 BC has elaborated the concept of *Vrana*. He not only gave an elaborate description of various types of wounds, but also presented a descriptive etiopathogenesis of wounds along with their management.^[4] *Lodhra* is described in classical Ayurvedic texts as absorbent, stomachic, refrigerant, astringent, expectorant and hemostatic. It is used single or in combination it helps wound healing.^[5] *Daruharidra* (Indian Barberry) *Sushruta* have mentioned it as *ropana* – a wound healer.

Daruharidra paste mixed with lime juice and salt peter and applied hot is popular application to sprain, bruises, wound and inflammatory joint diseases^[6] *Mochras* (Gum of Silk Cotton Tree/ *Bombax malabaricum*) proves remarkable wound healing activity.^[7] *Karpura* (Camphor) and *Teel Tel* (*Sesamum indicum*) has a very healing effect on the skin problems. It effectively controls the inflammation and pain and has a cooling and soothing effect.^[8-9] *Kokam* (*Garcinia indica*) pharmacologically studied for its antioxidative, chelating, free radical scavenging, anticancer, anti-inflammatory, and antiulcer activities are conducted.^[10-11] Anti-inflammatory and cooling effect of *Kokam* (*Garcinia indica*) helps in wound healing. Overall Ano spray claimed to provide good patient satisfaction, convenience and wound healing and less messy than solution, cream or powder.

CONCLUSION

Ano Spray is safe and superior to Betadine Solution in perineum wound healing.

ACKNOWLEDGEMENT

The author's would like to thank all the contributing clinicians and healing hands herbs Pvt Ltd. for their contribution.

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Cite this article as:

Porwal Ashwin, Gandhi Paresh, Deepak Kulkarni. An open label, randomized, comparative, parallel group, single center study to evaluate safety and efficacy of Ano spray in a comparison with Betadine Solution application in acute perineum wounds. AYUSHDHARA, 2017;4(6):1409-1412.

Source of support: Nil, Conflict of interest: None Declared

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