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A prospective comparison of topical feracrylum citrate versus adrenaline as haemostatic agent in hypospadias surgery in children

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ABSTRACT

Background: A comparative study of topical feracrylum citrate versus adrenaline to minimise haemorrhage-related complications in paediatric hypospadiac patients. **Patients and Methods:** A total of 108 consecutive paediatric hypospadiac patients (48 in the study group and 60 control — random allocation) were studied. In the study group, 1% feracrylum citrate solution was used and adrenaline (1:100,000) in controls. **Results:** Among the study group, average number of blood-soaked gauge pieces were 2.95/patient, correlating with average intraoperative blood loss of 14.74 ml. In controls, average blood-soaked gauge pieces were 4.83/patient corresponding to an average blood loss of 24.13 ml. The average amount of blood loss during surgery in the <5 years was 13.70 ml/patient in the feracrylum group, while the same in the adrenaline group was 23.45 ml. Average duration of surgery was 79 min in the study group, while the same in controls was 94 min/patient. Average number of cauterisations was 0.255/patient in the study group and 0.583/patient among controls. Postoperative haematoma was seen in 8% study group compared with 18% controls. Wound oedema appeared in 4.17% study group and 11.67% controls. Postoperative complications were higher among controls. **Conclusions:** Feracrylum is more efficient and safer topical haemostatic agent than adrenaline. It reduced the frequency of cauterisation and tissue damage, intraoperative blood loss, and postoperative complications.

Key words: Adrenaline, feracrylum citrate, haemostasis, hypospadias surgery

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INTRODUCTION

Hypospadias surgery is performed in children and more commonly in infants where loss of even small amount of blood can cause severe complications. The usual methods of haemostasis, e.g., cauterisation and ligation can cause tissue damage in children. Hence, there was a need of topical haemostatic agent with significant haemostatic property and minimum side-effects.

Feracrylum is a chemical haemostatic agent with no local side-effects, less cost, and good haemostatic property. Its use has been documented in many surgical fields. There has been only one previous study, which has evaluated the role of feracrylum in hypospadias surgery, but it was never compared with an established haemostatic agent. This is the first study of comparison of feracrylum citrate with adrenaline regarding its haemostatic and additional effects.

PATIENTS AND METHODS

This study was conducted on 108 consecutive paediatric hypospadias patients (6 months to 12 years age), (48 study group and 60 controls-random allocation) admitted in our hospital, who underwent different hypospadiac procedures for over 2 years from 2012 to 2013. To make data homogenous, patients were divided into different groups according to their age. The results were obtained in the entire group as well as <5 years age group to make study homogenous and remove age-related confounding factors present in higher age groups.

Among the study group, 1% feracrylum citrate solution was used during surgery to achieve haemostasis, via 10 cm × 10 cm, loose knit gauge pieces, each soaked in 2 ml of feracrylum solution, applied for 2-3 min, at the bleeding site, with moderate pressure. In the control

group, the same 10 cm × 10 cm loose knit gauge pieces were soaked in 2 ml adrenaline(1:100,000) and also applied for 2-3 min, with moderate pressure [Table 1].

All patients underwent the hypospadias surgery, by the same surgeons. All patients were administered the same antibiotics both pre-and post-operatively. Tourniquet was applied temporarily after regular intervals at the base of penis in all patients. All patients were assessed 3 days postoperatively and followed-up monthly after discharge.

We assessed the amount of blood loss during surgery, duration of surgery, frequency of cauterisation, wound oedema and postoperative complications in both groups-the study as well as the controls. According to our standardisation criteria, the average number of blood-soaked gauge pieces was converted into blood loss (in ml). A single 10 cm × 10 cm, loose knit gauze piece was found to absorb 5 ml of blood completely, on topical application over an oozing site, irrespective of the compound that the gauze was soaked in, calculated via the difference in weight before and after application.

Table 1: Agewise distribution of patients

Age group	1% feracrylum citrate (study) (%)	Adrenaline (1:100,000) (control) (%)	Total number of patients (%)
<5 years	29 (60.5)	37 (61.7)	66 (61.1)
5-10 years	16 (33.3)	15 (25)	31 (51.7)
>10 years	3 (6.3)	8 (13.3)	11 (18.3)
Total number of patients	48 (100)	60 (100)	108 (100)

RESULTS

Blood loss during surgery was assessed by the number of blood-soaked gauge pieces intraoperative, which were previously soaked in feracrylum (study) or in adrenaline (controls) followed by converted into average amount of blood loss during surgery (according to our prior standardisation criteria). Among the study group, the average number of blood-soaked gauge pieces was 2.95/patient (range 2-7) correlating with an average amount of blood loss during surgery of 14.74 ml. In the control group, the average number of blood-soaked gauge pieces was 4.83/patient (range 4-12) corresponding to an average amount of blood loss of 24.13 ml [Table 2].

As the most common group was <5 years age group, the data was analysed separately in this group to get the homogenous results.

In <5 years age group, among study group, the average number of blood-soaked gauge pieces was 2.76/patient correlating with an average amount of blood loss during surgery of 13.80 ml, while in the control group, the same was 4.84/patient corresponding to an average amount of blood loss of 24.20 ml [Table 3].

If we further analyse this data in larger Snodgrass group then the average number of blood-soaked gauge pieces in feracrylum group was 2.74/patient correlating with an average amount of blood loss during surgery of 13.70 ml while the same in the adrenaline group was 4.69 correlating with 23.45 ml blood loss.

Table 2: Surgerywise distribution of Patients

Type of surgery done	Feracrylum (study)			Adrenaline (control)		
	Number of gauze used	Number of patients	Average number of gauze	Number of gauze used	Number of patients	Average number of gauze
Stage I	19.5	7	2.79	45	9	5
Stage II	10	5	2	33	7	4.71
Snodgrass	98	34	2.88	188.5	41	4.60
Complex composite	14	2	7	23	3	7.67
Total	141.5	48	2.95	289.5	60	4.83

Table 3: Study of less than 5 years age group

Type of surgery done	Feracrylum (study)			Adrenaline (control)		
	Number of gauze used	Number of patients	Average number of gauze	Number of gauze used	Number of patients	Average number of gauze
Stage I	6	3	2	20	4	5
Stage II	5	2	2.5	15	3	5
Snodgrass	63	23	2.74	136	29	4.69
Complex composite	6	1	6	8	1	8
Total	80	29	2.76	179	37	4.84

The average duration of surgery was noted from time of incision up to wound dressing during every surgery. It was found to be 79 min in study group and 94 min in controls.

The average number of cauterisations were 0.255/patient in the study group (range 0-5), while they were 0.583/patient (range 3-14), among the controls.

Postoperative haematoma (irrespective of size) was seen in 3.33% of the controls while none of the patient in feracrylum group had this complication. Wound oedema appeared in 4.17% study group and 11.67% of controls. At the end of 2 years, 95% of patients are on follow-up.

DISCUSSION

Feracrylum is an incomplete ferrous salt (II and III) of polyacrylic acid, which acts as a topical haemostatic agent, for use in control of oozing in various surgical procedures.[1] It also possesses antimicrobial properties and decreases the postoperative infection. Its mode of action is via activation of thrombin, which subsequently causes conversion of fibrinogen to fibrin and thus clots formation. In addition, feracrylum combines with blood proteins, especially albumin and forms a gel-like substance, which forms a physical barrier on wound surface and stops capillary bleeding and oozing.[2] Feracrylum has molecular weight of 500,000-800,000 Daltons because of which it is not getting absorbed systemically and has no adverse effects on the liver, kidney, adrenals, cardiovascular and haemopoietic systems.[3]

The effectiveness of feracrylum in hypospadias surgery has been studied in only one study done by Lahoti *et al*.[4] However, it has never been compared with a traditional drug. This is the first study to compare the haemostatic effect of feracrylum in hypospadias surgeries with an established agent. In this study, feracrylum was used as the haemostatic agent in case group and comparison was done with adrenaline (1:100,000), which an established haemostatic agent.[5] We compared the benefits of feracrylum among study group as against controls.

On an average, blood loss during surgery in study group was 14.74 ml (average 2.948-gauge pieces) compared with 24.13 ml (average 4.825-gauge pieces) in controls. This signifies 9.39 ml less blood loss in study group than controls ($P < 0.0001$).

In <5 years age group, blood loss during surgery was 13.80 ml in study group as compared to 24.20 ml in control group. This signifies 10.4 ml less blood loss in feracrylum group ($P < 0.0001$).

If we further analyse this data in larger Snodgrass group then the average blood loss during surgery in study group was 13.70 ml, while the same in control group was 23.45 ml, which suggests 9.75 ml less blood loss in feracrylum group ($P < 0.0001$).

The two-tailed P value was found to be extremely significant in all the groups studied when amount of blood loss was taken as a variable. It suggests that feracrylum significantly reduces the amount of blood loss when compared with adrenaline.

The average duration of surgery in study group was 79 min while the same in control group was 94 min. The two-tailed P value is 0.0006, considered as extremely significant. This decrease in duration of surgery may be attributed to better haemostasis caused by 1% feracrylum citrate, which improves visual clearance of surgical field and hence speed of surgery.

Average number of cauterizations in study group was 0.255/patient (range 0-4) when compared to controls where average was 0.583/patient (range 0-16), denoting a statistically insignificant reduction in the average number of cauterisations ($P = 0.3066$). A larger sample size or more data is required for a statistically significant result. Postoperative hematoma was observed in only 8% patients (in study group) while, it was seen among 18% of controls, indicating a significant reduction in haematoma formation postoperatively ($P < 0.01$).

Wound oedema was observed around the periphery of the wound in only 4.17% study group when compared to controls, where it was found in approximately 11.67% patients. In majority of remaining patients mild to moderate oedema was present. In this study, approximately 3 times reduction in wound oedema was found among study group.

Many haemostatic agents have found to produce some side effects but on the contrary feracrylum was found to be very safe. Feracrylum is superior to povidone iodine for its antimicrobial properties.[6] In addition to its antimicrobial activity, feracrylum reduces the frequency of cauterizations, thereby decreasing the chances of tissue necrosis and postsurgical infection.[7] Infection was found in 2.08% (one patient) of study group and 8.33% (five patients) of controls, in our study. This indicates a 4 times reduction of infection in study group as compared to controls ($P < 0.223$). Devitalised skin flaps were only found in controls not in study group and that too in patients in whom postoperative infection was a complication ($P < 0.05$).

Urethrocutaneous fistulae (UCF) reported after hypospadias surgery result from failure of healing along the neourethral suture line. This healing is hampered due to the use of cauterization in the subcutaneous plane, as found in hypospadias surgery. A reduction in the frequency of cauterisations decreases tissue necrosis and improves the healing. In addition, its hygroscopic property also aids healing, thus reducing UCF occurrence. In our study, UCF occurred in 4.17% (two patients) in study group, while 11.67% (six patients) in controls, thus signifying a 3 times reduction, proving that it is safe to use feracrylum citrate as haemostatic agent in hypospadias surgery.

As can be seen from above, topical feracrylum solution application significantly reduces infection, UCF, meatal stenosis and stricture occurrence, thus proving beyond doubt that its application is advantageous. In this study, it is shown that feracrylum is an agent which not only controls bleeding but also reduces the frequency of cauterization and tissue damage, duration of surgery, blood loss during surgery and postoperative hematoma, wound oedema and postsurgical complications significantly.

Studies evaluating the use of this novel haemostatic agent in laparoscopic cholecystectomy, gastrointestinal bleeds, obstetric haemorrhage, reducing postoperative seroma formation in mastectomy have been conducted; however, large-scale and multicenter trials are mandatory to establish its efficacy in wider spectra of procedures.[8]

CONCLUSIONS

Feracrylum is thus an effective, safe, and dependable topical haemostatic agent. It reduces the frequency of cauterisation and tissue damage, blood loss during surgery, postoperative haematoma, wound oedema and postsurgical complications. It significantly minimises diffuse capillary oozing and surface bleeding, and thus obtains a clear field during surgery of hypospadias.

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