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EFFECT OF INTRANASAL DESMOPRESSIN SPRAY (SINGLE PUFF) ON HEMOSTASIS DURING FUNCTIONAL ENDOSCOPIC SINUS SURGERY: PROSPECTIVE RANDOMISED CLINICAL TRIAL

Anaesthesiology

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ABSTRACT

Background: Functional Endoscopic Sinus Surgery (FESS) is a widely employed intervention for sinonasal pathologies, occasionally complicated by hemorrhage, potentially affecting operative duration and outcomes. Various strategies have been explored to optimize surgical conditions, yet achieving consistent hemostasis remains challenging. This study investigates the efficacy of intranasal desmopressin spray in enhancing hemostasis during FESS, aiming to prevent intraoperative bleeding, improve surgical field quality, and mitigate postoperative complications. Methods: A prospective randomized controlled study spanned one and a half years at the Government Medical College, Jammu, enrolling 52 patients for Groups D (Desmopressin) and NS (Normal Saline). Blinded to assignments, participants underwent standardized premedication and were monitored for hemodynamic parameters, coagulation profiles, and potential side effects. Surgical field quality, blood loss, and postoperative complications were assessed using standardized scales and clinical measures. **Results:** Both the groups were comparable with respect to demographic variables (p-value>0.05). According to Boezaart scale; at the 15-minutes, bleeding scores showed no significant difference between groups ($p = 0.136$). However, at 60 minutes, Group D exhibited significantly lower bleeding scores ($p = 0.029$*). Group D also demonstrated a significantly lower mean blood loss (152.4 ml) compared to Group NS (217.5 ml) with a p-value below 0.001. Incidence rates of nausea, vomiting, headache, and epistaxis did not significantly differ between groups ($p > 0.05$). **Conclusion:** Premedication with intranasal desmopressin effectively reduced bleeding, enhanced surgical field quality, and resulted in manageable comparable postoperative complications during FESS. These findings support the potential of desmopressin as an adjunct in optimizing surgical outcomes in this context, warranting further exploration in diverse clinical scenarios.

KEYWORDS

Functional Endoscopic Sinus Surgery (FESS), General Anesthesia, Intranasal Desmopressin Spray, Hemostasis, Postoperative Complications.

INTRODUCTION

Functional Endoscopic Sinus Surgery (FESS) is a well-established surgical intervention employed in the management of various sinonasal pathologies. While instances of significant hemorrhage during Functional Endoscopic Sinus Surgery (FESS) are infrequent, a humid surgical field characterized by a limited volume of blood has the potential to extend the duration of the operation. This not only elevates the probability of encountering complications but may also lead to an incomplete surgical procedure.1,2 The intricacies of this procedure often necessitate meticulous hemostasis to optimize surgical visibility and mitigate potential complications associated with bleeding. In recent years, there has been a growing interest in exploring adjunctive pharmacological interventions to enhance hemostasis during FESS. Numerous methodologies have been proposed to enhance the operative environment in endoscopic sinus surgery, including controlled hypotension, application of topical vasoconstrictors, premedication involving alpha agonists, and the administration of antifibrinolytics .3-5Nevertheless, none of these strategies has demonstrated consistent efficacy in yielding an optimal, completely bloodless operative field for the surgical team. Achieving hemostasis during Functional Endoscopic Sinus Surgery (FESS) persists as a noteworthy challenge demanding attention and strategic consideration from both surgeons and anesthesiologists.

Desmopressin, scientifically denoted as 1-deamino-8-D-argininevasopressin, represents a synthetic analog of the antidiuretic hormone L-arginine vasopressin. Its pharmacological actions include elevating plasma concentrations of tissue plasminogen activator and endothelial factor VIII. Desmopressin's inaugural application traces back to 1977 when it was initially employed to mitigate bleeding risks during tooth extraction and surgical procedures in a patient diagnosed with hemophilia A.6 Following this pioneering use, extensive global studies ensued to elucidate both the therapeutic benefits and potential side effects associated with desmopressin. Recognizing its efficacy, the World Health Organization subsequently designated desmopressin as an indispensable anti-bleeding agent for individuals with hemophilia. Beyond its primary application, desmopressin has proven valuable in managing bleeding attributed to platelet abnormalities, congenital disorders, chronic kidney and liver conditions, as well as certain homeostatic dysfunctions.7 Extending beyond its conventional uses, desmopressin has been posited as a potential mitigator of intraoperative blood loss in individuals devoid of known coagulation abnormalities, particularly in the context of spine surgery.8,9 This prospective randomized clinical trial seeks to investigate the effect of intranasal desmopressin spray administered via a single puff on hemostasis during Functional Endoscopic Sinus Surgery (FESS). The primary goals are to prevent intraoperative blood loss, improve surgical field quality, and potentially shorten the surgical duration. Additionally, the study investigates the secondary aim of preventing postoperative complications. Group D (Desmopressin) will receive intranasal desmopressin, while Group NS (Normal Saline) serves as a control with intranasal normal saline premedication.

Methods

The present prospective randomized controlled study was undertaken at the Postgraduate Department of Anesthesiology, Government Medical College, Jammu, spanning a duration of one and a half years. Sample size determination was done by utilizing G-Power software, with 52 patients was requisite for the study to achieve 80% power, considering an effect size of 0.8 and a significance level of 5%. This sample was evenly randomly allocated to two groups: Group D (Desmopressin) and Group NS (Normal Saline), with 26 patients in each group. The surgeon, anesthesiologist, and anesthetic technician who were involved in the patient care were blinded to the nature of the study assignments. Ethical approval for this prospective randomized controlled study was obtained from the Institutional Ethics committee of the Government Medical College, Jammu, ensuring compliance with established ethical guidelines and principles. Informed consent was taken from all patients enrolled in the study. Patients were provided with detailed information about the study's objectives, procedures, and the random allocation into Group D (Desmopressin) or Group NS (Normal Saline).

The inclusion criteria for this study involved individuals experiencing chronic sinusitis and undergoing their initial Functional Endoscopic Sinus Surgery (FESS). Eligible participants include both sexes within

the age range of 18 to 60 years with American Society of Anesthesiologists (ASA) grades 1 and 2. Exclusion criteria included patient refusal, ASA grades 3 and 4, known desmopressin allergy, a history of hypertension, ischemic heart diseases, cerebrovascular diseases, or drug addiction, and patients on anticoagulants or with bleeding diathesis. Preanesthetic evaluation was performed, and upon arrival in the OT, intravenous access was established with an 18 G cannula, accompanied by BP and HR monitoring. Group D received a single puff of intranasal desmopressin, while Group NS received normal saline, 15 minutes before induction.

All patients underwent standardized premedication with injection Emeset (0.1mg /kg) and injection Tramadol (1-2 mg/kg) preoperatively. Preoxygenation done with 100 percent oxygen for 3-5 mins. Anesthesia induction with propofol (2 mg/kg) and atracurium (0.5 mg/kg), while maintenance with oxygen, nitrous oxide, sevoflurane, atracurium. Controlled mechanical ventilation maintained normocapnia, with an initial tidal volume of 8 mL/kg and respiratory rate of 12 breaths/min. Patient reversed with Injection Neostigmine (0.04mg/kg) and injection glycopyrolate (10 µg/kg) at the end of surgery. During intraoperative period fluid management included Ringer's lactate by Holliday-Segar method, and replacement of blood loss with Ringer's lactate solution in a 3:1 ratio. Patient positioning at a 10–15-degree reverse Trendelenburg angle, standardized anesthesia, and surgical techniques were maintained. Intraoperative blood loss assessment considered blood and irrigation fluid volumes in 25 mL suction canisters and nasopharyngeal packing, with the latter's weight measured on an electronic scale. The surgical field's quality was assessed at the 15th and 60th minutes using Boezaart et al.'s scale. Hemodynamic parameters, coagulation profiles, and potential side effects were monitored, with postoperative evaluations in the post-anesthesia care unit.

Statistical methods

The recorded data was compiled and entered in a spreadsheet (Microsoft Excel) and then exported to data editor of SPSS Version 20.0 (SPSS Inc., Chicago, Illinois, USA). Continuous variables were expressed as Mean ± SD and categorical variables were summarized as frequencies and percentages. Graphically the data was presented by bar diagrams. Student's independent t-test or Mann-Whitney U-test, whichever feasible, was employed for comparing continuous variables. P-value of less than 0.05 was considered statistically significant.

RESULTS

Table 1. provided a detailed examination of the demographic attributes and coagulation profiles of the study participants, categorized into two distinct groups: Group D and Group NS.

Parameter	Group D [n=26]	Group NS [n=26]	P-value
Age (Years)	40.3±7.38	39.5±6.59	0.639
Gender			
Male	19 (73.1%)	18 (69.2%)	0.759
Female	7 (26.9%)	8 (30.8%)	
ASA			
ASA I	21 (80.8%)	23 (88.5%)	0.701
ASA II	5 (19.2%)	3 (11.5%)	
Coagulation Preoperative PT (s)	11.9±1.87	12.4±2.14	0.309
Preoperative PTI (%)	92.1±3.17	93.4±3.46	0.112
Postoperative PT (s)	12.4±2.07	12.7±2.35	0.578
Postoperative PTI (%)	91.7±2.78	92.6±3.29	0.227

In terms of age distribution, the mean age for Group D was 40.3 years (±7.38), while for Group NS, it was 39.5 years (±6.59). Statistical analysis yielded a P-value of 0.639, indicating no significant difference in age between the two groups. The gender distribution revealed that 73.1% of Group D consisted of males, compared to 69.2% in Group NS. Females constituted 26.9% in Group D and 30.8% in Group NS; however, the difference in gender proportion between the groups was comparable with a p-value of 0.759. The American Society of Anesthesiologists (ASA) classification depicted that 80.8% of Group D fell under ASA I, while in Group NS, 88.5% had the same classification. Additionally, 19.2% of Group D was categorized as ASA II, contrasting with 11.5% in Group NS. However; with a p-value of 0.701 both the groups were comparable with respect to ASA status.

When the coagulation profile was evaluated we found that Group D exhibited a mean preoperative PT of 11.9 seconds (±1.87) compared to Group NS with 12.4 seconds (±2.14), yielding a non-significant P-value of 0.309. Similarly, the PTI percentages for Group D and Group NS were 92.1% (±3.17) and 93.4% (±3.46), respectively, with a non-significant P-value of 0.112. Postoperatively, the mean PT for Group D was 12.4 seconds (±2.07), while Group NS recorded 12.7 seconds (±2.35), resulting in a P-value of 0.578. Concurrently, the PTI percentages postoperatively were 91.7% (±2.78) for Group D and 92.6% (±3.29) for Group NS, yielding a non-significant P-value of 0.227.

Table 2: Bleeding score according to Boezaart scale in two groups at 15 and 60 minutes

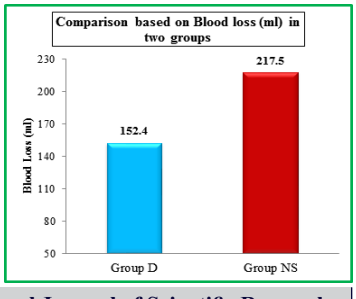
Time	Bleeding score	Group D [n=26]		Group NS [n=26]		P-value
		No.	%age	No.	%age	
At 15 minutes	1	13	50.0	7	26.9	0.136
	2	7	26.9	11	42.3	
	3	5	19.2	4	15.4	
	4	1	3.8	3	11.5	
	5	0	0.0	1	3.8	
	Median (IQR)	1.5 (1-2)		2.0 (1-3)		
At 60 minutes	1	15	57.7	7	26.9	0.029*
	2	8	30.8	8	30.8	
	3	3	11.5	10	38.5	
	4	0	0.0	1	3.8	
	5	0	0.0	0	0.0	
	Median (IQR)	1.0 (1-2)	3.0 (1-3)			

Table 2. presented bleeding scores according to the Boezaart scale at 15 and 60 minutes post-surgery for Group D (n=26) and Group NS (n=26). At the 15-minutes, Group D exhibited bleeding scores distributed as follows: Score 1 (50.0% in 13 individuals), Score 2 (26.9% in 7 individuals), Score 3 (19.2% in 5 individuals), Score 4 (3.8% in 1 individual), and no instances of Score 5. Group NS, in comparison, reflected bleeding scores of 26.9%, 42.3%, 15.4%, 11.5%, and 3.8% for Scores 1 through 5, respectively. The median bleeding score for Group D was 1.5 (IQR 1-2), while Group NS had a median score of 2.0 (IQR 1-3). The calculated P-value was 0.136, indicating no statistically significant difference between the groups at this time point. At the 60-minute juncture, Group D demonstrated bleeding scores: Score 1 (57.7% in 15 individuals), Score 2 (30.8% in 8 individuals), Score 3 (11.5% in 3 individuals), with no instances of Scores 4 and 5. In Group NS, the distribution was as follows: Scores 1 through 3 was respectively observed in 26.9%, 30.8%, and 38.5%, while Scores 4 and 5 was evidenced in 3.8% and 0% patients respectively. The median bleeding score for Group D was 1.0 (IQR 1-2), and for Group NS, it was 2.0 (IQR 1-3). The P-value at this time point was 0.029*, indicating a statistically significant difference between the bleeding scores of the two groups.

Table 3: Comparison based on Blood loss (ml) in two groups

Group	N	Mean	SD	95% CI	P-value
Group D	26	152.4	35.8	112.4-187.1	<0.001*
Group NS	26	217.5	46.5	160.1-274.9	

Table 3 compared blood loss (in milliliters) between two groups, namely Group D and Group NS. Group D demonstrated a significantly lower mean blood loss of 152.4 ml (SD: 35.8, 95% CI: 112.4-187.1), while Group NS, recorded a comparatively higher mean blood loss of 217.5 ml (SD: 46.5, 95% CI: 160.1-274.9). The observed p-value, which is less than 0.001, underscores the statistical significance of the difference in blood loss between the two groups (Fig. 1)

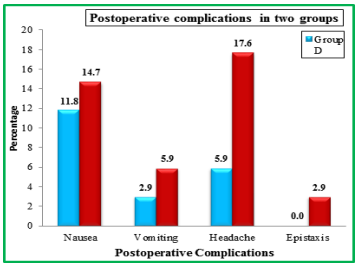


(Fig. 1)

Table 4: Postoperative complications in two groups

Complications	Group D [n=26]		Group NS [n=26]		P-value
	No.	%age	No.	%age	
Nausea	4	11.8	5	14.7	0.714
Vomiting	1	2.9	2	5.9	0.552
Headache	2	5.9	6	17.6	0.249
Epistaxis	0	0.0	1	2.9	1.000

Table 4 summarized the postoperative complications observed in two study groups, Group D and Group NS. For Group D, the incidence of nausea was 11.8%, vomiting was 2.9%, headache was 5.9%, and no cases of epistaxis were reported. In Group NS, the incidence of nausea, vomiting, headache, and epistaxis was 14.7%, 5.9%, 17.6%, and 2.9%, respectively. Statistical analysis revealed no significant differences ($p > 0.05$) between the two groups for any of the reported complications (Fig 2)



DISCUSSION

Hemorrhagic complications constitute a major challenge within the domain of functional endoscopic sinus surgery, exerting pronounced impacts on both patients and surgeons. From the patient perspective, these complications have the potential to increase hospitalization durations, augment healthcare expenditures, and detrimentally influence postoperative satisfaction and delay in recovery .[12,13] For surgeons, intraoperative bleeding complications wield the capacity to impede surgical field visibility, prolong procedural durations, consequently impacting surgical precision, and potentially compromising the overall quality of the surgical outcome.[13,14] The present study was conducted to assess the impact of administering intranasal desmopressin spray through a single puff on hemostasis during Functional Endoscopic Sinus Surgery (FESS). We observed that both the groups exhibited comparability concerning demographic variables and coagulation profile (p-value>0.05). Blood loss and the quality surgical field were determined in at 15 minutes and 60 minutes during the surgery (scoring by BOEZAART grading system). At the 15-minutes, bleeding scores in Group D and Group NS showed no significant difference (P=0.136), with median scores of 1.5 (IQR 1-2) for Group D and 2.0 (IQR 1-3) for Group NS. At 60 minutes, Group D exhibited significantly lower bleeding scores than Group NS (P=0.029*), with median scores of 1.0 (IQR 1-2) for Group D and 2.0 (IQR 1-3) for Group NS. This corroborates with a plethora of studies wherein surgeons consistently expressed higher satisfaction levels with the surgical field in the Desmopressin group compared to the control group. A study by Safaeian R et al concurred with our findings, indicating that the surgical field quality exhibited no statistically discernible discrepancy between the two groups at the 15-minute juncture, but a substantial disparity emerged after one hour.[2] Notably, findings by Franchini et al underscored that the onset of DDAVP efficacy necessitates approximately 30 minutes, with its influence enduring for a substantive duration of six to eight hours.[15] These collective outcomes accentuate that the quality of the surgical field lacked a statistically significant differentiation at the 15-minutes; however, a conspicuous distinction materialized after one hour, consistent with the findings of our investigation. Furthermore, Jahanshahi et al, in their comprehensive study, reported a significant impact of desmopressin on both blood loss and the quality of the surgical field across all evaluated intervals (15, 30, 60, and 90 minutes).[16] These outcomes fundamentally imply that a waiting period of approximately thirty minutes is imperative to discern the full clinical efficacy. Consequently, we support for the preemptive utilization of Desmopressin preceding anesthesia induction to elicit early-onset effectiveness throughout the initial stages of the surgical intervention. It is noteworthy that Desmopressin induces a sustained elevation in coagulation factors, persisting for approximately four hours. Given the relatively abbreviated duration of Functional Endoscopic Sinus Surgery (FESS), the proposition emerges that a singular intranasal Desmopressin administration of preceding the initiation of the surgical procedure would aptly fulfill our therapeutic objectives. This strategic approach aligns with the pharmacokinetic profile of Desmopressin, optimizing its clinical utility of the procedure like FESS and thereby enhancing its prophylactic efficacy in managing intraoperative bleeding.

In our study, Group D showed a notably diminished mean blood loss of 152.4 ml (SD: 35.8, 95% CI: 112.4-187.1), in contrast to Group NS, which recorded a comparatively elevated mean blood loss of 217.5 ml (SD: 46.5, 95% CI: 160.1-274.9). The derived p-value, falling below 0.001, underscores the statistical significance of the discerned disparity in blood loss between the two groups. These findings are accordingly with previous studies that accentuate the hemostatic advantages associated with desmopressin, as exemplified by Akbarpour M et al, Mannuccio P and Safaeian R et al.[2,16-18] Noteworthy among these was the study by Safaeian R et al, wherein the DDAVP group exhibited a mean blood loss of 147 ± 43 mL, contrasting with the placebo group's 212 ± 64 mL (mean ± SD, $P < 0.01$), thereby parallelizing our study outcomes.[2] Additionally, Jahanishi J et al reported a significant reduction in blood loss within the desmopressin group (mean±SD, 16.289±5.605 ml) in comparison to the control group (24.289±5.2722 ml, $P<0.001$), a finding that harmoniously concurs with the outcomes derived from our study.[18]In a randomized clinical trial conducted by Akbarpour, individuals selected for Functional Endoscopic Sinus Surgery (FESS) for bilateral chronic rhinosinusitis were systematically enrolled. The participants underwent random allocation into three groups: low-dose (20 µg) intranasal desmopressin (DDAVP), high-dose (40 µg) intranasal desmopressin, or a placebo. This allocation was done 60 minutes prior to the initiation of general anesthesia. While their study observed no significant difference in blood loss between the low-dose desmopressin and placebo groups, a notable divergence was evident between the high-dose desmopressin and placebo groups, demonstrating a mean difference of 29.6 ml (adjusted Cohen's d: −1.02; p < .001).[17] This observed distinction aligns with our study's findings; however, it's noteworthy that Akbarpour et al. employed two distinct doses of desmopressin in comparison to our singular dose approach. Similarly, an investigation led by Haddady and colleagues delved into the effects of a high dose (40 µg) of desmopressin on 17 candidates undergoing rhinoplasty. Their study reported a notable reduction in upper eyelid ecchymosis, Boezaart score, and intraoperative bleeding within the experimental group when contrasted with the placebo group.[19]

The administration of desmopressin, while presenting favorable hemostatic effects, necessitates a judicious consideration of potential side effects. It has been documented in the literature that the recurrent complications associated with desmopressin administration encompass a spectrum of physiological manifestations. Notably, tachycardia, facial flushing, nausea, headache, hyponatremia, and induction of seizures have been reported as common side effects. [23,24.] In Group D, the incidence of postoperative nausea stood at 11.8%, vomiting at 2.9%, and headache at 5.9%, with a notable absence of reported cases of epistaxis. Conversely, Group NS manifested incidence rates of 14.7%, 5.9%, 17.6%, and 2.9% for nausea, vomiting, headache, and epistaxis, respectively. Upon rigorous statistical scrutiny, the derived p-values surpassed the threshold of significance ($p > 0.05$) for all reported complications, signifying an absence of statistically significant differences between the two groups. Safaeian R et al, in their study, reported a parallel incidence of nausea, vomiting, and headache between the Desmopressin (DDAVP) and control groups, aligning cohesively with the findings observed in our study.[2] It is noteworthy that, akin to our methodology, the study did not specifically measure serum sodium levels. While previous clinical investigations have documented adverse effects of desmopressin, including hypertension, headache, water intoxication leading to hyponatremia, hyponatremic, convulsions, and abdominal cramps, these occurrences were typically associated with therapeutic doses (at least 20 µg per day) administered for durations exceeding 10 weeks.[18] In contrast, the present study observed parity in complication rates, indicating a comparable postoperative experience for individuals in both Group D and Group NS. This reinforces the null hypothesis, positing no significant differences in the incidence of nausea, vomiting, headache, or epistaxis between the two cohorts. The substantiation of this finding through rigorous statistical analysis enhances the broader understanding of the safety profile linked to the

interventions and underscores the study's robust design in discerning nuanced clinical outcomes. Despite these insights, further studies are warranted to comprehensively elucidate the implications of desmopressin administration in various clinical contexts.

CONCLUSION

The findings from this study affirm the efficacy of premedication with nasal spray desmopressin in achieving a significant reduction in bleeding and enhancing the surgical field during Functional Endoscopic Sinus Surgery (FESS). The observed improvements align with existing literature, supporting the hemostatic advantages associated with intranasal desmopressin spray in surgical settings. Importantly, the manageable and comparable postoperative complications observed in both study groups emphasize the safety profile of nasal spray desmopressin. The absence of substantial differences in complications underscores the drug's tolerability and further supports its consideration as a premedication option for patients undergoing FESS. However; further studies are warranted to elucidate the implications of desmopressin administration in various sssclinical contexts.

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