

Split-Body Double-Blinded Randomized Controlled Trial of Gelatin foam and Traditional Nasal Pack in Septal Surgery

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ABSTRACT: **OBJECTIVE:** To compare gelatin foam versus traditional nasal pack in terms of pain while in place and on removal. **STUDY DESIGN:** Split-body, double-blinded (patient and assessor blinded), randomized controlled trial. **PLACE AND DURATION OF STUDY:** Study was carried out in ENT Departments of Combined Military Hospital (CMH) Bahawalpur, Bahawal Victoria Hospital (BVH) Bahawalpur and CMH Multan from Jun 2009 to Jan 2011. **PATIENTS AND METHODS:** Patients with symptomatic deviated nasal septum undergoing an elective nasal septal surgery were selected and at the end of surgery one side of nose was packed with a traditional nasal pack (Bismuth iodoform paraffin paste- impregnated ribbon gauze/ paraffin-impregnated ribbon gauze/ paraffin gauze roll) and the other side was packed with gelatin foam. Randomization was done to allot traditional pack or gelatin foam pack to the incision side or non-incision side. The patients were kept blinded about the type of pack placed on each side. **RESULTS:** There was significantly less pain on removal of gelatin foam (mean pain score 1.35 on a visual analogue pain scale of 0 to 10 cm) as compared to traditional nasal pack (mean pain score 4.11; $P=0.01$). There was no significant difference in pain score between gelatin foam and traditional pack observed at 6 and 24 hours post-operatively ($P=0.08$ and 0.77 respectively). Both the packs were equally effective in preventing post-operative haemorrhage and septal hematoma. No crusting and adhesion formation was noted at the end of 2nd and 6th weeks with either of the packs. **CONCLUSION:** Gelatin foam pack is as effective as a traditional nasal pack in preventing post-operative bleeding and septal haematoma. There is no significant difference in pain due to presence of pack in nasal cavity but Gelatin foam causes significantly less pain on removal. There is no significant crusting and adhesion formation associated with either of these packs.

Key Words: Traditional nasal pack, Gelatin foam, Septoplasty.

INTRODUCTION: Nasal packing is done at the end of nasal septal surgery to prevent post-operative bleeding and septal hematoma. Options include traditional nasal packing, a pre-fabricated nasal sponge, an epistaxis balloon, or an absorbable biomaterial¹. Traditionally used nasal pack is paraffin gauze roll or ribbon gauze impregnated with paraffin/bismuth Iodoform paraffin paste (BIPP). Nasal packs are uncomfortable for the patient when in place and their removal is associated with a moderate to severe pain. Optimal form of nasal packing is not established and the quest for a painless nasal pack continues. The upcoming trend is to avoid packing if possible however it is not routinely practiced in South West Asia yet². Absorbable haemostatic agents are associated with a high degree of patient comfort and provide haemostasis comparable with traditional techniques³. Gelatin foam is being used as an alternative to traditional nasal packs. It liquefies within 5 to 7 days in a nasal cavity thus precluding a need for formal removal but we prefer to remove it by suction clearance on the 1st post-operative day thus restoring a nasal patency earlier⁴. We hypothesized that gelatin foam will be more effective than a conventional nasal pack in preventing bleeding and septal hematoma but will be

less painful while in-placed in nasal cavity and on removal.

PATIENTS AND METHODS: It was a multi-centric study carried out in ENT Departments of Combined Military Hospital (CMH) Bahawalpur, Bahawal Victoria Hospital (BVH) Bahawalpur and Combined Military Hospital (CMH) Multan from 11th Jun 2009 to 17th Jan 2011. Study plan was reviewed and approved by the ethical committees of all the three hospitals. An informed consent was taken to include the patients in the study. Patients with symptomatic deviated nasal septum (DNS) undergoing a septal surgery were registered. Children under 12 years of age, Patients undergoing surgery under local anaesthesia and those having a deranged coagulation profile or a known hypersensitivity to gelatin were excluded from the study. Also excluded from the study were the cases that required inferior turbinectomy or those who required posterior nasal packing. Septal surgery (sub mucosal resection/septoplasty) was performed with the usual technique under general anaesthesia. At the end of surgery one side of nose was packed with traditional nasal pack (BIPP-impregnated ribbon gauze/ paraffin-impregnated ribbon gauze/ paraffin gauze roll) and the other side was packed with haemostatic gelatin foam. A random number

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Mean pain score	Traditional pack	Haemostatic gelatin pack	P value (At 95% confidence interval of the difference)
6 hours post-operatively	2.64 (\pm 2.02)	1.7 (\pm 1.68)	0.08
24 hours post-operatively	2.23 (\pm 2.13)	1.23 (\pm 1.56)	0.077
On removal of pack	4.11 (\pm 2.44)	1.35 (\pm 1.65)	0.01

Table-1 : Mean Pain Score.

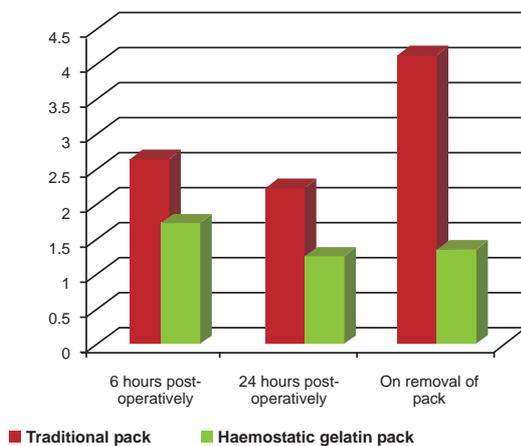


Chart-1 : Mean Pain Score.

table was used to allot traditional pack or gelatin foam pack on the incision side or non-incision side. The patients were kept blinded about the type of pack placed on each side. Packs were removed after 24 hours of surgery. Traditional pack was removed with the help of forceps and the gelatin foam was removed with the help of suction tip. The person assessing the outcome was kept blinded about the type of nasal pack on each side. The primary outcome measures were discomfort/pain due to the presence of packs in the nose (noted on a visual analogue scale of 0 to 10 cm at 6 hours after surgery and at 24 hours) and pain associated with their removal (noted on a visual analogue scale just after removal). Secondary outcome measures were post-operative hemorrhage (noted while the packs were in place and on removal; significant hemorrhage defined as bleeding requiring a re-packing), septal haematoma (assessed by anterior rhinoscopy after removal of pack), crusting and adhesion formation (assessed at the end of 2nd week and 6th weeks after the surgery on anterior rhinoscopy). The data was recorded on a specially designed performa and entered in Statistical Package for Social Sciences (SPSS) version 16 for analysis. Numerical data included age, pain scores at 6 hours, pain scores at 24 hours and pain scores on removal of packs. Qualitative data included gender, type of surgery, bleeding while packs in place, bleeding on removal of packs, crusting and adhesion formation after 2nd and 6th weeks. Mean and standard deviation was calculated for numerical data, and percentage was calculated for qualitative data. The comparison of gelatine foam pack and traditional pack was made regarding pain

score at 6 hours, 24 hours and on removal of pack. Statistical significance of observed difference was analyzed by applying paired sample t-test. Similarly comparison of gelatine foam pack and traditional pack was made in terms of bleeding (while pack is in place and on removal of pack), crusting and adhesion formation (after 2nd and 6th weeks). Observed difference was assessed for statistical significance through application of Chi square test. For both the numerical and quantitative data, after application of a test of significance, calculated P value equal to or less than 0.05 % was taken as significant. RESULTS: Demographics and clinical information Out of 84 patients 20 fulfilled the inclusion criteria and were enrolled in the study. Three (15%) were females and 17 (85%) were males. The minimum age was 16 years and maximum was 38 years. Mean age was 24.35 with a standard deviation of 5.57. Four patients underwent septoplasty (20%) and 16 patients (80%) underwent sub-mucosal resection of the nasal septum.

Main outcome measure : The main outcome measure was pain which was assessed on a visual analogue scale of 0 to 10 cm. It was recorded at 6 and 24 hours post-operatively and on removal of packs. Six hours after the operation mean pain score for traditional nasal pack was 2.64 with a standard deviation of 2.02. The mean pain score for haemostatic gelatin foam was 1.7 with a standard deviation of 1.68. This difference was not statistically significant (P value=0.08 at 95% confidence interval of the difference). Twenty four hours post operatively the mean pain for traditional pack was 2.23 with a standard deviation of 2.13. Similarly the mean pain for haemostatic gelatin foam is 1.23 with a standard deviation of 1.56. The observed difference is not statistically significant as the P value is not less than 0.05 (P value=0.077 at 95% confidence interval of the difference). The mean for pain on removal of traditional nasal pack was 4.11 with a standard deviation of 2.44. The mean pain for removal of haemostatic gelatin foam was 1.35 with a standard deviation of 1.65. This difference between mean pains is statistically significant as the P value is less than 0.05 (P=0.01 at 95% confidence interval of the difference). Main outcome measures are summarized in table 1 and chart 1.

Other outcome measures: There was no significant bleeding while packs were in place or on removal of packs in any of the patients. There was no septal hematoma in any of the patients. No significant crusting and adhesions were noted at the end of 2nd and 6th weeks post operatively.

DISCUSSION : Nasal packs are routinely placed after nasal septal surgery to prevent bleeding and septal hematoma. Pain caused by the nasal packs is a major concern and a quest for a painless nasal pack is still on³. This study was conducted to test the hypothesis that 'gelatin foam will be more effective than a conventional nasal pack in preventing bleeding and septal hematoma but will be less painful while in-placed in nasal cavity and on removal'. Pain is a subjective phenomenon and inter-individual variation in perception of pain is a major handicap in the trials involving pain as a variable. A split-body

study comparing the right side with the left in the same individual rules out inter-individual variation to some extent. As the right and left nasal cavities are innervated with separate nerves without significant overlap so we took this as an advantage to compare the pain on the right side with the left. Some other authors have also compared two different types of nasal packs in the same individual^{3,5,6,7}. Parhabu V et al allotted the two types of nasal packs between right and left side alternatively thus one type of pack was more likely to be placed in the non-incised nasal cavity, the side that would generally be expected to be associated with less pain⁷. We took care of this aspect and randomized the packs between incision side and non-incision side. The mean pain scores observed at 6 and 24 hours post-operatively were less with gelatin foam as compared to traditional nasal packs but the difference was not statistically significant ($P=0.08$ and 0.77 respectively). Similar studies comparing various types of nasal packs also showed minor differences in mean pain scores that were not statistically significant^{3,6,7}. This is because most of the packs caused only mild discomfort while in the nose. We observed that the mean pain score on removal of gelatin foam nasal packs was significantly less than traditional nasal packs (1.35 as compared to 4.11; $P=0.01$ at 95% confidence interval of the difference). Schoenberg et al also observed that routine nasal packs especially BIPP is associated with increased pain levels⁵. Chandra et al concluded that absorbable haemostatic agents are associated with a high degree of patient comfort³. According to Valentine et al traditional nasal packing is uncomfortable for patients thus absorbable biomaterials are being commonly used after endoscopic sinus surgery, both for haemostatic and wound healing considerations⁸. When applied to nasal mucosa gelatin foam liquefies within 2 to 5 day^{4,9}. However it is recommended by some authors that the left over material should be debrided with suction clearance¹⁰. We recommend that the gelatin foam should be completely removed after 24 or 48 hours as it has full-filled its purpose and is no more needed. It will not only restore the nasal patency but will also minimize potential chances of a toxic shock syndrome. The removal of gelatin foam with suction clearance was well tolerated by the patients in our study. The mean pain score for removal of gelatin foam (1.35) was less than the mean pain score due to presence of gelatin foam in the nasal cavity at 6 hours (1.7) and slightly more than the mean pain score due to presence of gelatin foam in the nasal cavity at 24 hours (1.23).

In our study both gelatin foam and traditional nasal packs were equally effective in preventing bleeding and septal hematoma. Chandra et al also concluded that absorbable haemostatic agents provide haemostasis comparable with traditional techniques³. Different studies comparing various types of nasal packs showed that most of the packs served the purpose well in preventing bleeding and septal haematoma^{3,6,7}. We looked for crusting and adhesion formation at the

end of 2nd and 6th post-operative weeks and did not find significant crusting or adhesion formation with either type of nasal packs under study. No significant difference in incidence of adhesions and crusting was noted in studies comparing Rapid Rhino versus Telfa packs and Merocel versus Spiggel packs^{6,7}. In another study there was no significant difference in the incidence of adhesions between the groups which received traditional removable packs and those who did not receive any pack⁵. So we can say that the removable packs do not significantly alter adhesion formation or crusting tendency of nasal mucosa. However different self-resorbable biomaterials may incite an inflammatory reaction and may induce differential patterns of mucosal healing, potentially causing increase in crusting and adhesion formation^{3,8}. A study comparing thrombin-soaked gelatin and FloSeal (a novel absorbable haemostatic paste used as a nasal pack) showed that FloSeal had clear trends toward increased granulation tissue ($p = 0.007$) and adhesion ($p = 0.006$) formation as compared to thrombin soaked-gelatin foam³.

CONCLUSION: Gelatin foam pack is as effective as a traditional nasal pack in preventing post-operative bleeding and septal haematoma. There is no significant difference in pain due to presence of pack in nasal cavity but Gelatin foam causes significantly less pain on removal. There is no significant crusting and adhesion formation associated with either of these packs.

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