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5 Fluorouracil: Does It Impact Postoperative Nasal Adhesion

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Abstract:

Introduction: Adhesions are one of the most common complications after endoscopic nasal surgery and cause of functional endoscopic sinus surgery revision. 5-Fluorouracil has been used by many medical specialties to reduce different adhesions and epithelial growth-related complications.

Aim and objectives: To Evaluate the effect of topical 5-fluorouracil application in the nasal cavity on preventing nasal adhesions after endoscopic partial inferior turbinectomy combined with septoplasty and to compare it with the results of only packing with silastic sheets in the contralateral side.

Subjects and methods: We selected 30 patients who are suffering from chronic nasal obstruction due to hypertrophied inferior turbinate and deviated nasal septum indicated for endoscopic partial inferior turbinectomy combined with Septoplasty, presenting to the Al -Azhar University hospitals (Al-Hussein & Sayed Galal).All patients were subjected to complete clinical examination after history taking, then Endoscopic examination and Computed Topography to nose and Paranasal sinuses.Postoperative follow-up for 6 months after septoplasty and partial inferior turbinectomy.

Results: There was no statistically significant difference on application of silastic or 5-Fluorouracil in both groups along 6 months follow-up except at one week postoperatively.

Conclusion: We concluded that 5-FU is a good method for prevention of postoperative complications mainly adhesions formation and postoperative pain, headache and nasal obstruction in the 1st week postoperatively giving higher degree of safety.

Keywords: Fluorouracil, Inferior turbinate hypertrophy, Septoplasty, Silastic.

Introduction:

The nasal surgeries aim at removing nasal obstruction, improving nasal air flow, curing disease and facilitating sinus drainage thus improve nasal breathing but may cause minimal tissue damage. Tissue damage may be in the form of direct tissue injury intraoperative or indirect abnormal healing as adhesion formation postoperatively [1].

Endoscopic sinus surgery (ESS) has been accepted as the preferred treatment for chronic sinus disease. This is because this method preserves the sinus mucosa, establishes a sinus detoxification method and a drainage system from natural pores and eliminates disease effectively [1].

The effectiveness of ESS has been clearly defined over the past two decades, however, the shrinkage and formation of post-ESS adhesions is a possible cause of surgical failure [2].

Empty packing and drug packing have been shown to reduce the formation of synechiae after surgery[3].

The postoperative adhesion in the middle meatus is the most common complication after ESS with incidence rate 11% to 36%. This leads to blocking the normal sinuses mucociliary drainage pathway and disease recurrence [4].

Multiple techniques have been used to prevent postoperative synechiae formation as nasal packing in the middle meatus, suture medialization and partial resection of the middle turbinate [5].

The use of 5-FU as an antimetabolic agent in endoscopic dacryocy storhinostomy surgery was effective and it can decrease adhesions and stenosis in ESS [6].

5-Fluorouracil (5-FU) has been used by many medical specialties to decrease different adhesions and epithelial growth-related complications. It is used safely in ophthalmology to increase the survival of trabeculectomy and is also used in dermatology to treat actinic keratosis [7].

So, this study aimed to evaluate the effect of topical 5-fluorouracil application in the nasal cavity on preventing nasal adhesions after endoscopic partial inferior turbinectomy combined with septoplasty and to compare it with the results of only packing with silastic sheets in the contralateral side.

Methods:

This study included 30 patients who presented to the Otorhinolaryngology out-patient clinic at Al-Azhar University hospitals (Al-Hussein& Sayed Galal) during the period from July 2021 till January 2022.Those patients complaining of bilateral nasal obstruction due to inferior turbinate hypertrophy and deviated nasal septum were subjected to a sufficient evaluation including history taking and clinical examination; to select those who were included in this study and underwent the operative procedures. All cases diagnosed as inferior turbinate hypertrophy and deviated nasal septum on the basis of the clinical features, CT scans and nasal endoscopic examination. All patients had persistent nasal obstruction in spite of systemic and local treatment for more than 3 months.

This study was conducted on 30 patients. Patients were classified into two groups. Group A (n=15) in which the 5-fluorouracil pack (1ml 5-FU diluted with 9 ml of saline solution 0.9%) was applied in the

nasal cavity (at killian incision side) while Silastic sheet at the contralateral side and Group B (n=15) in which the silastic sheets were applied at (killian incision side) while 5-fluorouracil at contralateral side.

Inclusion criteria were1. Patients aged 18 years-old or more.2. Sex: both genders.3. Only those who underwent bilateral endoscopic partial inferior turbinectomy in a combination with septoplasty.

Exclusion criteria were1.Patients with uncontrolled systemic illness as DM and hypertension.2.Pre-existing septal perforation or adhesions.3.Previous history of nasal surgery.4.Age group less than 18 years old.5.Unilateral nasal surgery6.Patients with traumatic nasal deformity , cysticfibrosis, abnormalities of cilia transport as Kartagener's syndrome.

Both groups were subjected to: **1-Thorough history taking.2-complete clinical examination either by anterior rhinoscopy or nasal endoscopic examination. 3-Radiological assessment via CT nose and PNS**. **4-Laboratory investigations:**CBC, LFTs, KFTs, Bleeding profile.

The operation was done under general hypotensive anaesthesia using Karl Storz 0º rigid nasal endoscope. The nasal cavity was decongested using cottonoids soaked with adrenaline 1/200,000 solution for 10 minutes. All patients had 1- Endoscopic assisted submucous resection of the nasal septum technique then partial inferior turbinectomy technique (under endoscopic vision).

To obtain a concentration of 5 mg/ml of 5- FU: 1 mL of 5-FU (1000 mg/20 mL) was diluted with 9 mL of 0.9% saline. Then injection of 1 mL diluted 5-FU (5 mg/mL) in the merocel nasal pack to be soaked after its insertion in the nasal cavity between inferior turbinate and nasal septum under direct endoscopic visualization.

At the end of a combined endoscopic inferior turbinoplasty with Septoplasty surgery , nasal packing was done as follow:

-Group A (15 patients) : Tampon soaked in 5-flurouracil was applied in one side of nasal cavity (the side of killian’s incision) and silastic sheet was applied in the contralateral side followed by insertion of merocel nasal packing .

-Group B (15 patients) : silastic sheet was applied in the(side of killian’s incision) followed by insertion of merocel nasal packing and Tampon soaked in5-flurouracil was applied in the contralateral side of nasal cavity (between septum& inferior turbinate))

Postoperative care and follow up was as following: The nasal pack was removed after 48 hours. The silastic sheet was removed after 7 days. All patients received oral antibiotics and analgesic for 7 days, alkaline nasal wash for 2 months and nasal decongestant for 3 days. All Patients were followed up in the outpatient clinic over a period of six months as follow: (one week, two weeks, one month, three months and six months). Follow up was conducted via assessment of symptoms and nasal examination using rigid endoscope. The assessment of symptoms has been focused on evaluating the presence of nasal obstruction, headache, discharge, pain and smell change. The physical examination has been focused on evaluating the presence of nasal adhesions, crustations and discharge.

Ethics and patient consent: All procedures followed Al-Azhar university ethical committee regulations, taking the consent from all patients.

Statistical analysis: Microsoft Excel software was used to code, enter, and analyze data obtained while taking the history, essential clinical examination, laboratory tests, and outcome measures. The data was then imported into Statistical Package for the Social Sciences (SPSS version 20.0) software for analysis. According to the data type, qualitative data is represented as number and percentage, and the continuous quantitative data is represented by mean ± standard deviation (SD). The following tests were used to test differences for significance: Differences between frequencies (qualitative variables) and percentages in groups were compared by the Chi-square test. P-value was set at <0.05 for significant results and < 0.001 for highly significant results.

Results:

This randomized prospective comparative study was conducted on 30 patients with bilateral hypertrophied inferior turbinate and deviated nasal septum.

Patients were randomly classified into two groups: Group A (15 patients) : Tampon soaked in 5-flurouracil was applied in one side of nasal cavity (the side of killian's incision) and silastic sheet was applied in the contralateral side. Group B (15 patients) : silastic sheet was applied in the(side of killian's incision) and Tampon soaked in 5-flurouracil was applied in the contralateral side of nasal cavity (between septum& inferior turbinate)

Tables 2, 3 and figures 1, 2 showed the assessment of both groups in the first 6 months postoperatively as following:

-At one week postoperatively, there were no cases with nasal adhesions neither in 5-fluorouracil nor silastic sides in both groups.

-At two weeks postoperatively, adhesions were observed in three cases(20%) in 5-fluorouracil side in group A& two cases(13.3%) in group B but there were 4 cases (26.7%) with nasal adhesios in silastic side in group A & 3 cases (20%) in group B

-At one month postoperatively, adhesions were observed in three cases(20%) in 5-fluorouracil side in group A& two cases(13.3%) in group B but there were 2 cases (13.3%) with nasal adhesios in silastic side in group A & two cases (13.3%) in group B

-At three months &six months postoperatively, there were no cases with nasal adhesions neither in fluorouracil nor silastic sides in both groups.

All cases with adhesions treated with removal of adhesions by scissor ordissector under local anaesthesia and all cases relieved from adhesions.

Table 4 and figure 3, 4assessed pain as our patients were reevaluated forpain 7 days postoperatively as following:

-Group A had only 2 cases (13%) with postoperative pain at 5-FU side& 10 cases (66%) at silastic side during application of silastic and relieved after removal of it.

-Group B had only 3cases (20%) with postoperative pain at 5-FU side& 11 cases (73%) at silastic side during application of silastic and relieved after removal of it.

Discussion:

Adhesion's formation and ostial stenosis are common complications after ESS with incidence rate 11–36%. It is mainly due to contact between raw mucosal surfaces during wound healing [8].

This study was done on 30 patients suffering from chronic nasal obstruction due to hypertrophy of the inferior turbinate and deviated nasal septum not responding to medical treatments. Their ages were ranging from 18 to 45 years with a mean age of 32.96 ±5.78 years. Thirteen patients were male and 17 patients were female. These patients were divided into two groups: 15 patients in group A and 15 patients in group B. There was no statistically significant difference between both groups as regards age, sex and preoperative data.

All subjects were evaluated and treated with surgical intervention in the form of endoscopic partial inferior turbinectomy combined with submucous resection of the nasal septum followed by nasal packing was done as follow :

Group A (15 patients) : Tampon soaked in 5-flurouracil was applied in one side of nasal cavity (the side of killian's incision) and silastic sheet was applied in the contralateral side followed by insertion of merocel nasal packing. Group B (15 patients) : silastic sheet was applied in the(side of killian's incision) followed by insertion of merocel nasal packing and Tampon soaked in 5-flurouracil was applied in the contralateral side of nasal cavity (between septum& inferior turbinate).

Our study was designed to evaluate the effect of topical 5-fluorouracil application in the nasal cavity on preventing nasal adhesions after endoscopic partial inferior turbinectomy combined with septoplasty and to compare it with the results of only packing with silastic sheets in the contralateral side.We compared most postoperative data as, adhesions nasal obstruction, headache, discharge, dryness, pain, smell affection and crustations.

As regards postoperative adhesions, there was no statistically significant difference between both 5-FU side & Silastic sheet side in both groups A & B regarding postoperative adhesions and also no statistically significant difference in 5-FU side either it was applied at side of Killian incision or not p-value=0.851 (table no 5). At one week postoperatively, there were no cases with nasal adhesions neither in 5-fluorouracil nor silastic sides in both groups. At two weeks postoperatively, adhesions were observed in three cases(20%) in 5-fluorouracil side in group A& two cases (13.3%) in group B but there were 4 cases (26.7%) with nasal adhesions in silastic side in group A & 3 cases (20%) in group B. At one month postoperatively, adhesions were observed in three cases (20%) in 5-fluorouracil side in group A& two cases (13.3%) in group B but there were 2 cases (13.3%) with nasal adhesions in silastic side in group A & two cases (13.3%) in group B. At three months &six months postoperatively, there were no cases with nasal adhesions neither in fluorouracil nor silastic sides in both groups. All cases with adhesions

treated with removal of adhesions by scissor or dissector under local anesthesia and all cases relieved from adhesions.

Nuseir (2017) revealed that there was statistically significant difference between fluorouracil side and saline side regarding postoperative adhesions. On the 1st week postoperative follow-up on 69 patients, adhesions were observed in 24 Patients (35%), bilaterally in 6 patients (9%), unilaterally in 18 patients (26%) (only 3 (4%) in 5-FU sides and 15 (22%) in saline sides). On the 8th follow up week, adhesions were observed in 21 Patient (36%) bilateral in 2 patients (3%), unilateral in 19 patients (33%) (only 4 (7%) in 5-FU sides and 15(26%) in saline sides). On the 1st week postoperative follow-up on 69 patients, adhesions were observed in 24 Patients (35%), bilaterally in 6 patients (9%), unilaterally in 18 patients (26%) (only 3 (4%) in 5-FU sides and 15 (22%) in saline sides). On the 8th follow up week, adhesions were observed in 21 Patient (36%) bilateral in 2 patients (3%), unilateral in 19 patients (33%) (only 4 (7%) in 5-FU sides and 15(26%) in saline sides) [9].

Veluswamy (2012) have shown that the use of intranasal splints in septal surgery significantly reduced formation of postoperative nasal adhesions (2.5%) as compared to simple nasal packing (12.5%) [10].

As regards postoperative nasal obstruction, at one week postoperatively, there were no cases with nasal obstruction in fluorouracil side in both groups but there were 7 cases (47.7%) with nasal obstruction in silastic side in group A & 8 cases (53.3%) in group B during application of silastic sheet and relieved after removal of it. At two weeks postoperatively, there were two cases (13.3%) with nasal obstruction in fluorouracil side in both groups but there was one case (6.7%) with nasal obstruction in silastic side in group A & 2 cases (13.3%) in group B due to excessive nasal crustations treated with removal of crusts in out-patient clinic and use of nasal irrigation with alkaline nasal douches at home. At one month postoperatively, there were two no cases with nasal obstruction in fluorouracil side in both groups but there were 1 case (6.7%) with nasal obstruction in silastic side in group A and two cases (13.3%) in group B due to nasal adhesions treated with cutting adhesions with scissor under local anesthesia. At three months &six months postoperatively, there were no cases with nasal obstruction neither in fluorouracil nor silastic sides in both groups.

Our study showed that postoperative nasal obstruction was significantly higher in silastic side than fluorouracil side in both groups at the 1st week postoperatively due to presence of silastic sheets but there was no statistically significant difference between both sides at two weeks, one month , three months and six months postoperatively.

As regards postoperative headache, at one week postoperatively, there were no cases with headache in 5-FU side in both groups but there were 9 cases (60%) with headache in silastic side in group A & 8 cases (53.3%) in group B during application of silastic sheet and relieved after removal of it. At two weeks postoperatively, there were two cases (13.3%) with headache in 5-FU side in both groups but there were 3 cases (20%) with headache in silastic side in group A & 4 cases (26.7%) in group B . At one month postoperatively, , there were 1 case (6.7%) with headache in 5-FU side in group A & 2 cases(13.3%) in group B but there were 2 cases (13.3%) with headache in silastic side in group A & 3 cases (20%) in group B. At three months &six months postoperatively, there were no cases with nasal obstruction neither in fluorouracil nor silastic sides in both groups.

All cases with headache at two weeks and one month postoperatively weredue to sinusitis and relieved completely with medical treatment for two weeks(antibiotics, analgesics, nasal decongestants and mucolytics).

Our study showed that postoperative headache was significantly higher in silastic side than fluorouracil side in both groups at 1st week postoperatively but there was no significant difference between both sides in both groups at two weeks, one month, three months and six months postoperatively.

As regards postoperative discharge, at one week postoperatively, there were no cases with nasal obstruction neither in fluorouracil nor silastic sides in both groups. At two weeks postoperatively, there were two cases(13.3%) with nasal discharge in 5-FU sidein group A& 3 cases (20%) in group B but there were 3 cases (20%) with discharge in silastic side both groups.

At one month postoperatively, , there were 1 case (6.7%) with nasal discharge in 5-FU side both groups but there were 2 cases (13.3%) with discharge in silastic side both groups. At three months &six months postoperatively, there were no cases with nasal obstruction neither in fluorouracil nor silastic sides in both groups. All cases treated with antibiotics, analgesics, nasal decongestants and mucolytics and relieved completely with medical treatment for two weeks.

As regards postoperative crustations, at one week postoperatively, there were 15 cases (100%) with crustations in 5-FU side in both groups but there were 10 cases (66.7%) with crustations in silastic side in group A& 11 cases (73.3%) in group B. At two weeks postoperatively, there were 6 cases (40%) with crustations in 5-FU side in both groups but there were 4 cases (26.7%) with crustations in silastic side in group A& 5 cases (33.3%) in group B. At one, three & six months postoperatively, there were no cases with crustations influorouracil nor silastic sides in both groups. All cases with crustations treated with removal of crusts in out-patient clinic using Tilley Dressing Forceps and nasal irrigation with alkaline nasal douches at home.

Our study showed that postoperative crustations were significantly higher in fluorouracil side than silastic side at the 1st week postoperatively but there was no statistically significant difference between both sides in both groups at two weeks, one month, three months and six months postoperatively.

In our study, there was no statistically significant difference between 5-FU side & silastic side in both groups regarding nasal obstruction, headache, discharge, smell change, dryness and crustations after the 1st week follow up (after removal of silastic sheets).

This agrees with the results of the study of Nuseir (2017) in their prospective controlled study on 69 patients to evaluate the effect of 5-FU on post-operative complications after endoscopic inferior turbinoplasty combined with one or more other nasal surgeries, found that there was no significant difference between 5-fluorouracil side and saline side in nasal obstruction, headache, discharge, smell change, and crustations [9].

Osama (2014) study on using intranasal septal splint after partial inferior turbinectomy (PIT), found that there was no statistically significant difference between splinted and non-splinted groups in nasal obstruction, headache, discharge, smell change and crustations [11].

As regards postoperative pain, there was statistically significant difference between 5-FU side & silastic side in both groups regarding post-operative pain, Group A had only 2 cases (13%) with postoperative pain at 5-FU side& 10 cases (66%) at silastic side during application of silastic and relieved after removal of it P-value 0.003 .Group B had only 3cases (20%) with postoperative pain at 5-FU side& 11 cases (73%) at silastic side during application of silastic and relieved after removal of it (P-value 0.004) .

This agrees with the results of the study of Amjad (2017) in their retrospective study on sixty patients who underwent septoplasty procedure without any other nasal surgery. Sixty adults patients were randomly categorized into two equal groups, one group with silastic sheets and the other group without silastic sheets. No nasal packing was used for all patients. This study showed that silastic sheets significantly increased the postoperative pain and nasal discomfort during removing them one week after surgery [12].

Osama (2014) showed that the use of intranasal splints after partial inferior turbinectomy without septal surgery can increase postoperative pain in the short-term follow-up period [11].

Understanding the complex anatomy of the nasal cavity, paranasal sinuses and ostiomeatal complex help to decrease iatrogenic trauma, enhances preservation of the mucosa so as to reduce adhesion formation. Prevention of adhesions formation starts in the operating room by avoiding mucosal stripping and removal of bone fragments. Also, the use of the modern microdebrider preserves the mucosa and minimizes the presence of bone fragments and remnant tissues [13].

Conclusion:

According to our data and statistical analysis, we found that 5-FU application is an easy, effective and safe method in decreasing and preventing formation of adhesions as silastic sheet whatever it was applied at side of Killian incision or at the contralateral side with a significant less postoperative pain, headache and nasal obstruction than silastic in the 1st week postoperative when applied during endoscopic partial inferior turbinectomy combined with submucous resection of the nasal septum. We believe that 5-FU is a good method for prevention of postoperative complications mainly adhesions formation and postoperative pain, headache and nasal obstruction in the 1st week postoperatively giving higher degree of safety. We encourage other surgeons to expand our experience with 5-fluorouracil.

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Individual author's contribution:

El-Gammal MAA: Whole work of the study.

ElsamnodyAN: Continuous supervision on whole work and guidance of selection of cases and broad instructions.

Zowei lTM: Direct supervision and close monitoring of cases.

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Tables:

Variables	Group 1	Group 2	Test value	P-value
Age Mean± SD	31.93±5.43	33.99±5.78	1.006	0.323[1]
Gender Male n (%) Female n (%)	7 (47.7%) 8 (53.3%)	6 (40%) 9 (60%)	1.023	0.987[2]

Table 1Demographic data

1: student t-test 2: chi-square test, BMI: body mass index

Nasal adhesions Group B	5-FU SIDE (n=15)	Silastic SIDE (Killian incision) (n=15)	Test value	P-value
At one week follow up	0 (0%)	0 (0%)	0.000*	1.000
At two weeks follow up	2 (13.3%)	3 (20%)	0.235*	0.628
At one month follow up	2 (13.3%)	2 (13.3%)	0.000*	1.000
At 3 months follow up	0 (0%)	0 (0%)	0.000*	1.000
At 6 months follow up	0 (0%)	0 (0%)	0.000*	1.000

Table 2Comparison between both sides regarding postoperative adhesions during the first 6 months postoperatively in group B

*Chi-square test

Nasal adhesions	5-FU SIDE (n=15) (group A)	5-FU SIDE (n=15) (group B)	Test value	P-value
At one week follow up	0 (0%)	0 (0%)	0.000*	1.000
At two weeks follow up	3 (20%)	2 (13.3%)	0.235*	0.628
At one month follow up	3 (20%)	2 (13.3%)	0.235*	0.628
At 3 months follow up	0 (0%)	0 (0%)	0.000*	1.000
At 6 months follow up	0 (0%)	0 (0%)	0.000*	1.000

Table 3Comparison between 5-FU side in both groups regarding postoperative adhesions during the first 6 months postoperatively

*Chi-square test

Pain	5-FU SIDE (killian incision) (n=15)	Silastic SIDE (n=15)	Test value	P-value
Group A			8.614	0.003*
Yes	2 (13.3%)	10 (66.7%)		
NO	13 (86.7%)	5 (33.3%)		
Group B			8.276	0.004*
Yes	3 (20%)	11 (73.3%)		
NO	12(80%)	4(26.6%)		

Table 4 Comparison between both sides regarding postoperative pain

*Chi-square test

Figures legend

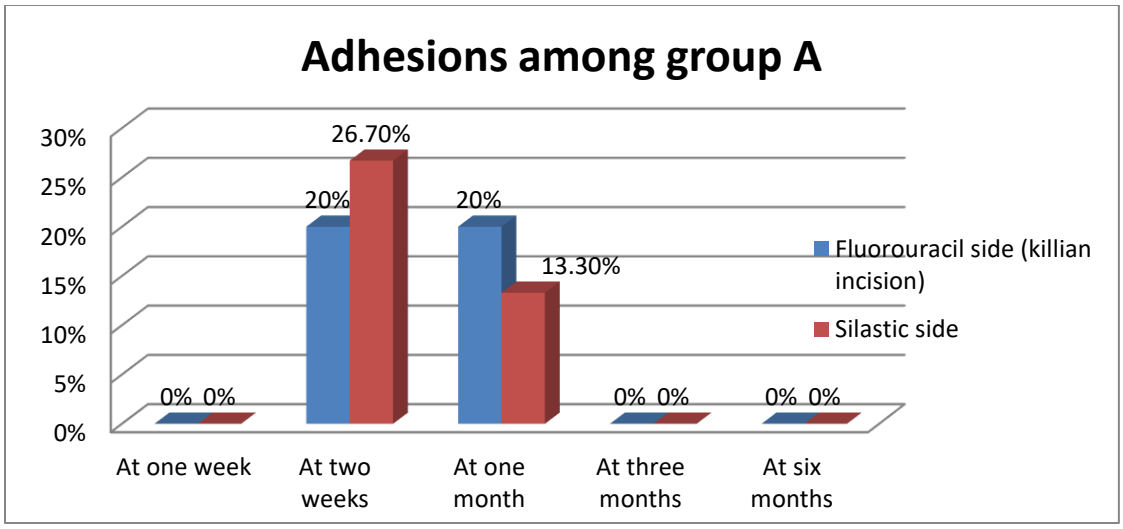

Figure (1): post-operative adhesions among group A.

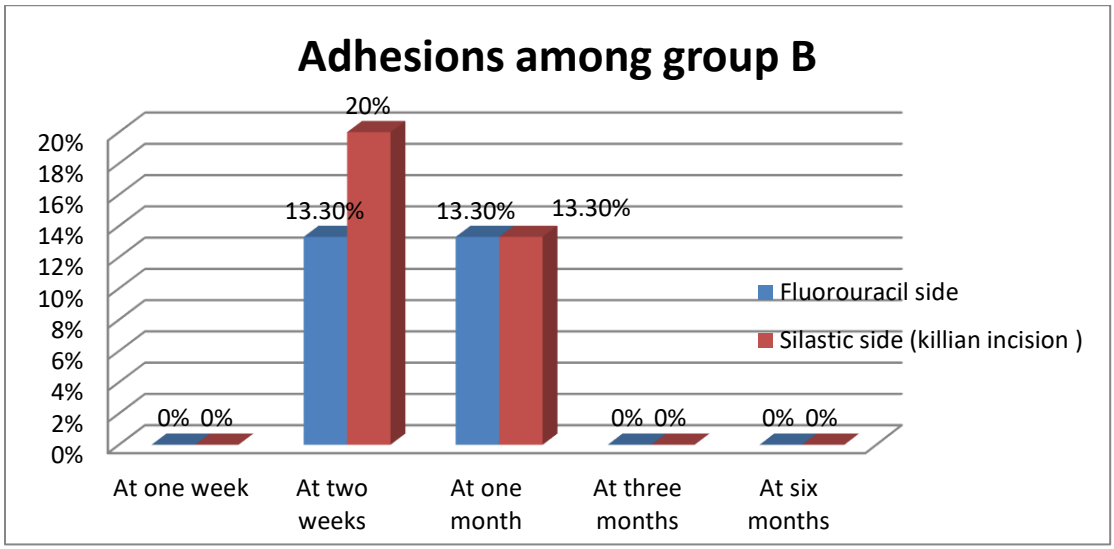

Figure (2): post-operative adhesions among group B.

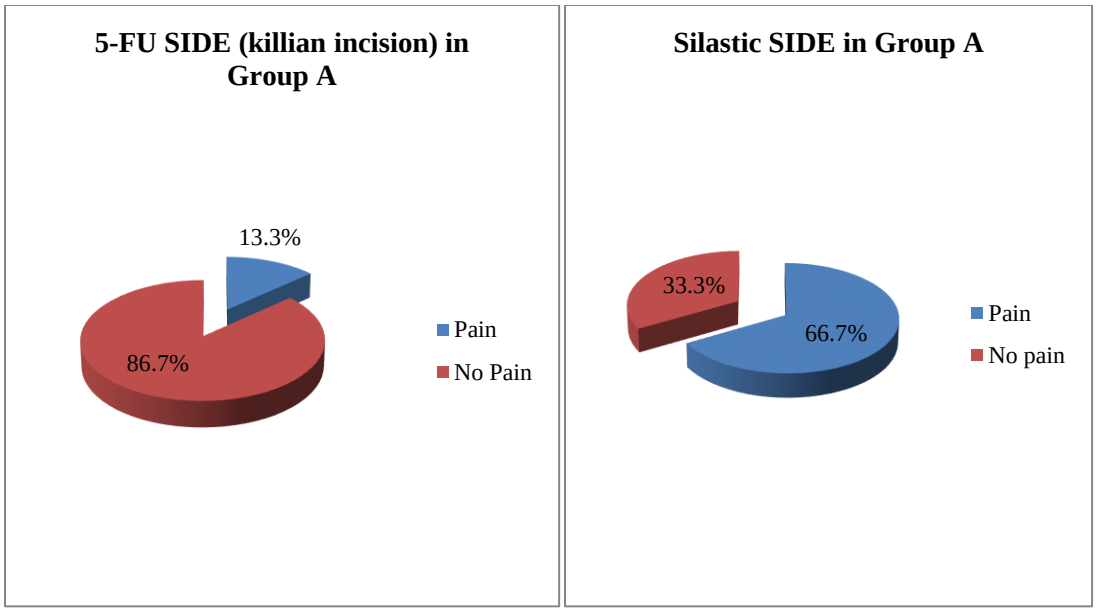

Figure (3): post-operative pain among group A.

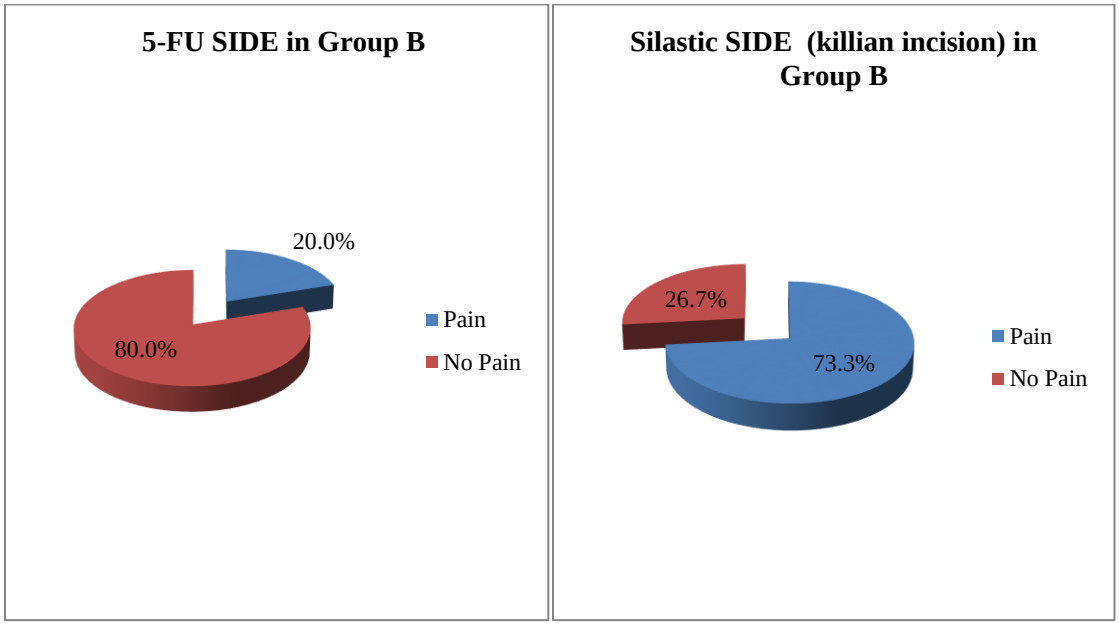

Figure (4): post-operative pain among group B.