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Comparative study of use of Lactulose (Duphalac) and Agarol post-operatively in Anorectal surgical conditions

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Abstract

Introduction: Constipation is one of the major problem worldwide. It is main problem after ano-rectal surgeries. So use of laxatives is increasing all over the world to get relieve from constipation. here, we are studying the comparison of effect of Lactulose and Agarol in postoperative cases of anorectal surgeries .
Material and methods: The results are based on a study of total of 50 patients, out of which 25 cases of ano-rectal surgical conditions, were put on Lactulose and 25 patients of ano rectal surgical conditions put on Agarol post-operatively. All cases were operated upon in the surgical wards of the Guru Nanak Dev Hospital. Amritsar attached to the Govt. Medical College, Amritsar. All the patients included in study who underwent surgery were examined and relevant medical history and demographic details were recorded. Patients with congenital ano-rectal anomalies and with malignant ano-rectal disorders were excluded from the study.
Results: The comparison was made according to Age, Sex, Chief complaints, Duration of symptoms, Amount of stool, Number of times stool passed, Stool consistency, Family history, Benign Anorectal conditions, Type of Operation done, Time taken during Operation, Relief of constipation, Reduction in the dose, Pain during defecation, Stopping the use of Analgesia, Bleeding per rectum, Mucus discharge per rectum, Pruritis Ani, Side effects and Result of operation. The effects of both were recorded on a tabulated performa.
Conclusion: Lactulose is better tolerated than Agarol when used postoperatively in cases of ano-rectal surgeries.

Keywords: Constipation, Lactulose and Agarol , anorectal surgeries.

Introduction

Majority of the people in this world suffer from constipation which may be ranging from very mild to severe. Constipation is thus a common reason for consultation in primary care. Most of the benign ano-rectal conditions are related with constipation which may be a predisposing factor or a sequelae of these ano-rectal conditions.1

Constipation following abdominal surgery is one of the major concerns of the physician. Any straining during defecation can lead to disruption of surgical sutures and result in dehescence of surgical wound. Hence to maintain soft faeces, use of laxatives becomes, many a times, imperative in patients after abdominal surgery.2

The various ano-rectal conditions thought to be related with constipation and requiring surgery can be enlisted as benign tumours of the rectum, familial adenomatous polyposis, Hurschprung's disease, prolapse of rectum, imperforate anus-high or low type, anal fissure, hypertrophied anal papilla, ano-rectal abscesses, fistula in ano and primary or secondary piles. All these ano-rectal conditions are often associated with or accompanied by constipation which may cause pain, bleeding per rectum, tenesmus, altered bowel habits, mucus discharge, pruritis ani etc.3

Laxatives are grouped as bulk producers, saline laxatives, stimulant laxatives, lubricant laxatives, stool (faecal) softners etc. Bulk producers tops the list of laxatives as they were used in old ancient times and are the pioneers amongst the laxative groups. Bulk producers, mainly used as laxatives are, unprocessed bran, refind preparation of ispagul husk or seeds, stirculia gum (Kuraya), Kanormal, carboxymethyl cellulose, sodium-calcium polycarbothyl, plantago (phyllium), agar, methyl cellulose, legnin. cabbage fibres etc. Saline laxatives are high osmolarity compounds and attract water into the lumen of the intestines. All patients undergoing surgery for the mentioned ano-rectal surgical conditions require laxatives for smooth, painfree, bleeding free and complete evacuation of bowel. Many types of laxatives are used post operatively in these ano-rectal surgical conditions. Agarol was mainly used in this Guru Nanak Dev Hospital, Amritsar attached to the Govt. Medical College. Amritsar.

In this study, a comparative study was undertaken to evaluate the pros & cons of Lactulose and Agarol in post operative anorectal surgical conditions.4 A total of 50 patients from surgical wards of Guru Nanak Dev Hospital, Amritsar attached to Govt. Medical College, Amritsar was taken and divided into two groups of 25 cases each. Group A consisted of those patients, who were prescribed Lactulose and group B constituted patients taking Agarol . Patients with congenital ano-rectal anomalies and with malignant ano-rectal disorders were excluded from the study.

Preoperatively each patient was assessed for the various parameters related to the constipation e.g. history of constipation, history of painful defecation, history of sense of incomplete evaluation, heaviness, rectal bleeding, pruritis ani, discharge per-rectum, duration of these symptoms, number of stools passed/day/week, amount of stool passed and stool consistancy etc.

It was also started preoperatively and continued for the period required by the patient. Post operatively patients were evaluated for symptoms like constipation, or sense of incomplete evacuation, pain during defecation, bleeding per-rectum. discharge per-rectum, pruritis ani, side effects of laxatives if any, reduction in the dose of laxative and reduction in the dose of analgesics on the first, second, third postoperative day, at the time of discharge from the hospital and then at one week, two weeks, three weeks and three months after discharge from hospital postoperatively. At the end of treatment, patients were rated in-terms of relief of their symptoms in the scale (excellent, good. poor).

Materials and Methods

In this comparative study, a total of 50 patients from Surgical Wards of Guru Nanak Dev Hospital attached to Government Medical College, Amritsar were taken. These were divided into two groups of 25 each. Group A consisted of those patients receiving Duphalac (Lactulose) and Group B constituted patients taking Agarol .

The study medication Duphalac (Lactulose) was administered in a dose of 30 ml per day in divided doses to group A. This daily dosage was adjusted after 2 days according to the response. The dose increased or decreased by one table spoon ful depending on the response, in terms of stool frequency and consistency.

Similarly Agarol was administered in a dose of 15 ml per day in the divided doses to group B patients. This daily dosage was increased or decreased by 5 ml depending upon the response.

All the patients included in study who underwent surgery were examined and relevant medical history and demographic details were recorded. In local examination ano-rectal conditions like piles, their position, anal fistula, anal fissure, rectal polyp etc noted and recorded.

Patients were investigated preoperatively from the point of anaesthesia. Postoperatively, duphalac (lactulose) and Agarol were given at bed time to each group of cases to allow easy motion in the next morning. Antibiotics were given for seven days postoperatively.5 Postoperatively patients were evaluated for symptoms like constipation or sense of incomplete evacuation, pain during defecation, bleeding per-rectum discharge per-rectum, pruritis ani, side effects of laxatives if any, reduction of dose of laxatives and reduction of dose of analgesics on 1st, 2nd and 3rd postoperative day and at the time of discharge and then after one week. 2 weeks, 3 weeks and 3 months.

Results

The results are based on a study of 25 patients of ano-rectal surgical conditions, put on Lactulose and 25 patients of ano rectal surgical conditions put on Agarol operated upon in the surgical wards of the Guru Nanak Dev Hospital. Amritsar attached to the Govt. Medical College, Amritsar.

The comparison was made according to Age, Sex, Chief complaints, Duration of symptoms, Amount of stool, Number of times stool passed, Stool consistency, Family history, Benign Anorectal conditions, Type of Operation done, Time taken during Operation, Relief of constipation, Reduction in the dose, Pain during defecation, Stopping the use of Analgesia, Bleeding per rectum, Mucus discharge per rectum, Pruritis Ani, Side effects and Result of operation. The compaison in various variables was not found significant. The Significant comparison is discussed below.

Table 1 Assessment of 50 patients put on Lactulose and Agarol according to relief of constipation (passed stools)

	Relief of constipation with Lactulose	%age	Relief of constipation with Agarol	%age
1st day	3	12	5	20
2nd day	11	44	11	44
3rd day	24	96	13	52
D.O.D.	25	100	18	72
1* week after D.O.D	-	-	20	80
2nd week after D.O.D	-	-	22	88
3rd week after D.O.D	-	-	25	100
3rd month after D.O.D	-	-	-	-

The above said table clearly indicates the effect of lectulose and Agarol in relieving constipation post operatively. Patients were put on respective laxatives only one day before operation because of their short stay in the hospital pre-operatively. The Agarol group showed improvement early but because of the stool softening effect of Lactulose, the Lactulose group then showed tremendous relief of constipation and almost entire group was free from constipation on 3rd day (96%) whereas in the Agarol group relief from constipation was only 72% at the time of discharge from hospital and three patients continued to take Agarol upto 2 weeks postoperatively.

Table 2 distribution of 25 cases in each group according to reduction in the dose of Laxatives and Agarol

	Lactulose dose reduction in number of Patients	%age	Agarol dose reduction in number of patients	%age
1st day	3	12	5	20
2nd day	11	44	11	44
3rd day	24	96	13	52
D.O.D.	25	100	18	72
1st week after D.O.D	-	-	20	80
2nd week after D.O.D	-	-	22	88
3rd week after D.O.D	-	-	24	96
3rd month after D.O.D	-	-	25	100

P value : <0.001 at 3rd day and <0.001 at date of discharge

In this table. Lactulose group showed a sharp decline in short interval and the dose of laxative reduced to nil dosage after a week time at the time of discharge of the patients from hospital (100%). whereas in Agarol group there was a slow reduction in dosage of laxatives postoperatively (72%) and two patient remained on laxative in the postoperative period upto 3rd week after the discharge from the hospital. The results on the 3rd post-operative day and at date of discharge were <0.001 and <0.001 respectively, which were statistically highly significant.

Table 3 Distribution of 50 patients on Lactulose and Agarol according to pain during defecation

	Lactulose Group	%age	Agarol group	%age
1st day	2	8	5	20
2nd day	6	24	9	36
3rd day	2	8	12	48
D.O.D.	1	4	7	28
1st week after D.O.D	-	-	5	20
2nd week after D.O.D	-	-	3	12
3rd week after D.O.D	-	-	2	8
3rd month after D.O.D	-	-	1	4

P value : <0.001 or 3rd day and <0.001 at the date of discharge

As shown in above table pain during defecation in Lactulose group decreased from 2nd day onwards due to stool softening effect of Lactulose and Agarol group showed very slow decrease in the painful defecation. On 4% patients of Lactulose were complaining of painful defecation at the time of discharge from the hospital whereas 28% of the patients in Agarol group were complaining of painful defecation at the time of discharge from the hospital. When the Chi square test was applied, the statistical values in Lactulose and Agarol group were found to be <0.001 and <0.001 respectively on 3"1 post-operative day and at date of discharge which were statistically highly significant.

Table 4 Assessment of 25 cases in each group according to bleeding per rectum

	Lactulose group	%age	Agarol group	%age
1st day	1	4	4	16
2nd day	3	12	8	32
3rd day	1	4	6	24
D.O.D.	-	-	3	12
1st week after D.O.D	-	-	2	8
2nd week after D.O.D	-	-	I	4
3rd week after D.O.D	-	-	-	-
3rd month after D.O.D	-	-	-	-

P value: <0.05 on 1st day, <0.001 on 2nd, 3rd and at date of discharge

As tabulated in the above table, on comparison of both groups, the Lactulose group showed negligible number of patients complaining of bleeding per-rectum after 2nd day onwards, largely due to stool softening effect of Lactulose, whereas in Agarol group, scanty bleeding per-rectum at time of defecation was complained of by three patients at the time of discharge from the hospital and one patient even complained of decreased bleeding per-rectum even in 2nd week post-operatively though it was just spotting.

After applying chi square, the statistical values (p value) on 1st , 2nd ,3rd post-operative day and at time of discharge were <0.05, <0.001. <0.001 and <0.001 respectively. It shows that it is significant on 1SI post-operative day and statistically highly significant on 2nd, 3rd and at the date of discharge.

Table 5 Distribution of 25 cases in each group according to mucous discharge per-rectum

	Lactulose group	%age	Agarol group	%age
1st day		-		-
2nd day	-	-	-	-
3rd day	-	-	-	-
D.O.D.	1	4	2	8
1st week after D.O.D	-	-	3	12
2nd week after D.O.D	-	-	3	12
3rd week after D.O.D	-	-	2	8
3rd month after D.O.D	-	-	1	4

P values: >0.05 at date of discharge and <0.001 after one week of DOD

As is clear from the above table that only one patient complained of mucus discharge per-rectum on the date of discharge in Lactulose group whereas significant number of patients complaining of mucus discharge pcr-rectum in Agarol group of patients, probably due to use of the laxatives for a quite long time postoperatively.

When chi square test applied statistical values found to be <0.05 and <0.001 at the date of discharge and at P1 week after date of discharge of the patients showing there by that it is not significant at date of discharge but it is statistically highly significant at one week after date of discharge.

Table 6 Distribution of 25 cases in each group according to pruritis ANI

	Lactulose group	%age	Agarol group	%age
1st day		-		-
2nd day	-	-	-	-
3rd day	-	-	-	-
D.O.D.	1	4	2	8
1st week after D.O.D	-	-	3	12
2nd week after D.O.D	-	-	3	12
3rd week after D.O.D	-	-	2	8
3rd month after D.O.D	-	-	I	4

P value >0.05 on date of discharge, <0.001 on 1* week after DOD

This table shows that pruritis ani in Lactulose group at the time of discharge from hospital was present in one patient only and that too for short interval of time which subsided later on due to complete freedom from constipation with Lactulose. On the contrary Agarol group complained of pruritis ani in increased number of patients for a long time.

On applying Chi square, the statistical values was found to be >0.05 at the time of discharge of the patient which was not significant, but p value was <0.001 at one week after discharge of the patient which was statistically highly significant.

Table 7 Distribution of 25 cases in each group according to side effects

	Lactulose group	Percentage	Agarol group	Percentage
Drug reaction	-	-		-
Urticarial rash	-	-	-	-
Nausea vomiting	I	4	3	12
Pain abdomen	I	4	L	4
Acute/subacute intestinal obstruction				
Diarrhoea	-	-	-	-

P value <0.05 for nausea, vomiting and >0.05 for pain abdomen

There were very few side effects of both the Agarol and Lactulose that also very mild. Only one patient of Lactulose group complained of nausea vomiting whereas three patients of Agarol reported similar complaints. Pain abdomen was very mild in both groups, that too was observed only in one patient in each group.

When Chi square applied, statistical value was found to be <0.05 in relation to nausea, vomiting which was statistically significant which shows that the Lactulose is less nauseating and induced less vomiting. The p value was not significant in relation to pain abdomen in both the group of patients showing there by that both the Lactulose and Agarol are equal in relation to pain abdomen post-operatively.

As a whole Lactulose group had a very few side effects postoperatively whereas Agarol group had significant post-operative side effects postoperatively.

Table 8 Distribution of 25 cases in each group according to the results of operation

	Lactulose group	Percentage	Agarol Group	Percentage
Excellent	24	96	16	64
Good	1	4	8	32
Poor	-	-	1	4
Total	25	100	25	100

P value <0.00

As calculated in the above table, the observations showed excellent results 96% in Lactulose group compared to the 64% excellent in Agarol group.

On applying chi square test, statistical value was found to be <0.001 in relation to the results of Lactulose and Agarol postoperatively, proving that the value is highly significant. This confirms that statistically Lactulose is much more effective and superior to the Agarol in reducing the various parameters, post-operatively as confirmed already. This clearly shows that Lactulose is much superior to Agarol in benign ano rectal surgical conditions post operatively.

Discussion

In this study a total of 50 patients of benign ano-rectal surgical conditions as haemorrhoids, anal fistula, anal fissure and rectal polyps, admitted in the Surgical Department of Guru Nanak Dev Hospital, Amritsar attached to Govt. Medical College, Amritsar were taken up. These were divided into two groups of 25 each. Group A consisted of those patients receiving lactulose and group B constituted patients taking Agarol. Patients with congenital ano-rectal anomalies in children and patients suffering from malignant disorder were excluded from the study. . The following points of study have been found significant to assess the efficacy of laxatives post-operatively in benign ano-rectal conditions:-

According to relief of constipation.
According to reduction in dose.
According to pain during defecation.
According to bleeding per rectum.
According to mucous discharge.
According to pruritis ani.
According to side effects.
According to results of operation

As shown in table 1, most cases first bowel action followed on 1st or 2nd postoperative day. Lactulose patients were free from constipation i.e. all patients on Lactulose passed motion at the time of discharge from the hospital (100%), where as Agarol group was free from constipation at the time of discharge from hospital only in less number of patients (72%).6

As enlisted in table 2, all patients taking Lactulose were passing stools with ease, no pain, no bleeding per-rectum without sense of incomplete evacuation at the time of discharge from hospital in the Lactulose group probably due to stool softening effect of Lactulose whereas in Agarol group, patients continued to use laxatives for quite a long time post-operatively.7-8

In Table 3 showed decrease in the pain during defecation in each group post operatively. In Lactulose group painful defecation decreased from 2nd postoperative day onwards due to stool softening effect of Lactulose. Agarol group showed very slow decrease in painful defecation post-operatively and 28% of the patients were complaing of painful defecation at the time of discharge from the hospital, compared to the 4% of the patients in laculose group. One patient complained of painful defecation even upto 3 weeks postoperatively in Agarol group, though clinical examination in this patients did not reveal anal fissure, anal stenosis, abscess or any other cause for his painful defecation.

As described in table 4, there was a marked difference between two groups regarding bleeding pcr-rectum post operatively. Patients put on Lactulose had no bleeding per-rectum after the 3"1 post-operative day, whereas Agarol group patients continued to have bleeding per- rectum upto the 2n<l week post-operatively. This could be due to early bowel action, stool softening effect of Lactulose which reduces friction and anal stretching effect of hard stools, thereby minimising bleeding per-rectum.9

As indicated in table 5, post operative mucus discharge was minimal, in the Lactulose group. Only one patient complained of mucus discharge per-rectum in the Lactulose group. In Agarol group significant number of patients continued mucus discharge per-rectum post-operatively probably due to prolonged use of Agarol postoperatively.10
As is clear from the table 6, pruritis ani is minimal in Lactulose group whereas it is significant in Agarol group, because pruritis ani is related with the mucus discharge per-rectum postoperatively. As mucus discharge has continued for a long time in Agarol group, pruritis ani also continued for a long time post-operatively.11

Table 7, shows the side effects of both Lactulose and Agarol . Only one case of Lactulose group (4%) C/O nausea and vomitting whereas three patients (12%) in Agarol group reported similar complaints. Pain abdomen was very mild in both groups and only one patient in each group C/O very mild pain abdomen for short time. This indicates that laculose is well tolerated and has a better compliance compared to the Agarol , there by proving its efficacy in the management of benign ano-rectal surgical patients postoperatively. 12

Table 8 shows observation regarding results of the study in this series of patients. Excellent results were depicted in 96% of patients receiving Lactulose compared to the 64% excellent results in Agarol group. These results clearly showed superiority of Lactulose over Agarol in its better toleratbility, better compliance, almost negligible reduced mucus discharge per-rectum, reduced pruritis ani, early evacuation of bowel there by reducing bleeding per-rectum, reducing painful defecation, and so reducing the dose of analgesics and laxatives at a much earlier time.13-14 The reduction in the various parameters was probably due to the stool softening effect of Lactulose, by which stools become soft, bulky and well formed, normalising, colonic transit and hence improving stool frequency and consistency.

Conclusion

The effect of two laxatives i.e. Lactulose and Agarol were studied in 50 patients of benign anorectal surgical condition in the post operative period. The study confirmed the efficacy and safety profile of both the laxatives. However Lactulose showed a better improvement in anal symptoms such as rectorrhagia. pain during defecation, feeling of incomplete evacuation and ensured normal stool consistency and strain free defecation as compared to the Agarol.

An improvement in the signs and symptoms associated with surgery of these ano-rectal surgical conditions viz pain on defecation, rectal bleeding, pruritis ani, rectal discharge, and feeling of heaviness at one week of treatment postoperatively in the Lactulose group was superior to that of Agarol group.

It was also observed that stool parameters like stool consistency and frequency of stools also showed significant improvement, in the Lactulose group of patients in comparison to Agarol group of patients. A noteworthy feature of this study has been that most of the signs and symptoms assessed have shown improvement in the first week DOD in Lactulose group as compared to the Agarol, who were having signs and symptoms even upto three weeks postoperatively.

It was concluded that Lactulose is superior to Agarol in the management of ano-rectal surgical conditions postoperatively. The relief of constipation, painful defecation, reduced bleeding per rectum, less doses of analgesics and laxatives was observed in early post operative period with Lactulose group as compared to Agarol. The mucous discharge and pruritis ani was not seen in any case receiving Lactulose. However both laxatives are well tolerated in both patients.

Conflicts of interest: None

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