Results

The Results

In this prospective randomized study which includes 60 patients divided into 3 groups (A, B and C) each has 20 patients.

Results during the procedure

Problems during anastomosis

In group A: thick oedematous bowel wall was found in 3 cases (15%).

In group B: thick bowel wall was found in 2 cases (10%). Difficulty in application of BAR in 2 cases (10%).

In group C: difficult application of the stapler at a very low colo rectal anastomosis 1 case (5%).

In comparison between group B & C in difficulty of application of anastomosis the p value > 0.05 non significant.

In manual anastomosis cutting through the wall of the bowel occur in 3 cases due to oedematous friable wall which avoided by proper tightening of the note and suitable size of suture material. Thick friable wall was encountered occur also in 2 cases in stapler group which lead to improper closure of the staples which can be avoided by choosing the proper size of the staples.

Difficult application of TA staples occured in one case at lower 1/3 of the rectum due to bulky uterus with a relatively narrow pelvis with massive adhesion.

Insertion of the BAR into intestinal lumen may be associated with some difficulties or with mucosal or submucosal tears. This occur in

2cases, such complication could be avoided by proper training & suitable size of the BAR device.

Table (2): Type of resection & Anastomosis (Fig. 47)

Group / Type of anastomosis	Group A		Group B		Group C		P value
	No	%	No	%	No	%	
Ileo-transverse a. EE after right Hemicolectomy	4	20	5	25	3	15	> 0.05
Ileo-sigmoid a. EE or SS after subtotal colectomy	2	10	2	10	1	5	> 0.05
Ileo –rectal a. SS after total colectomy	-	-	-	-	1	5	> 0.05
Colo-colic a. EE after left Hemicolectomy	1	5	-	-	6	30	0.05
Colo- rectal a. EE or ES after anteriar Resection	8	40	13	65	9	45	>0.05
Closure of colostomy (simple loop)	3	15	-	-	-	-	
1ry closure of the colon	2	10	-	-	-	-	
Total	20	-	20	-	20	-	

EE= End to End SS = Side to side a= anastomosis ES= End to side

The P value between the different groups of the study p> 0.05 is non significant.

Anastomotic time (Fig. 48)

Table (3): Time needed for anastomosis

Time needed to complete the anastomosis	ranged from (minutes)	average (mean)
Group A	25-48	34
Group B	13-28	18
Group C	20-40	30

Table(4):

Studied group / Time for anastomosis	(A) Manual no =20	(B) Valerie no=20	(C) Stapler no=20
$\bar{X}$	34	18	30
± SD	±2.41	±1.08	±2.23

$\bar{X}$ Mean value, ± SD Standard Deviation.

- In comparison between group A & B, the P value is < 0.01 (Highly significantly
- Also in comparison between group A & C, the P value > 0.05 (non significantly).
- Between group B&C the P value P <0.01 Highly significant.

Operative time (Fig. 49)

Table(5): calculate from the start of skin incision to the end of skin closure

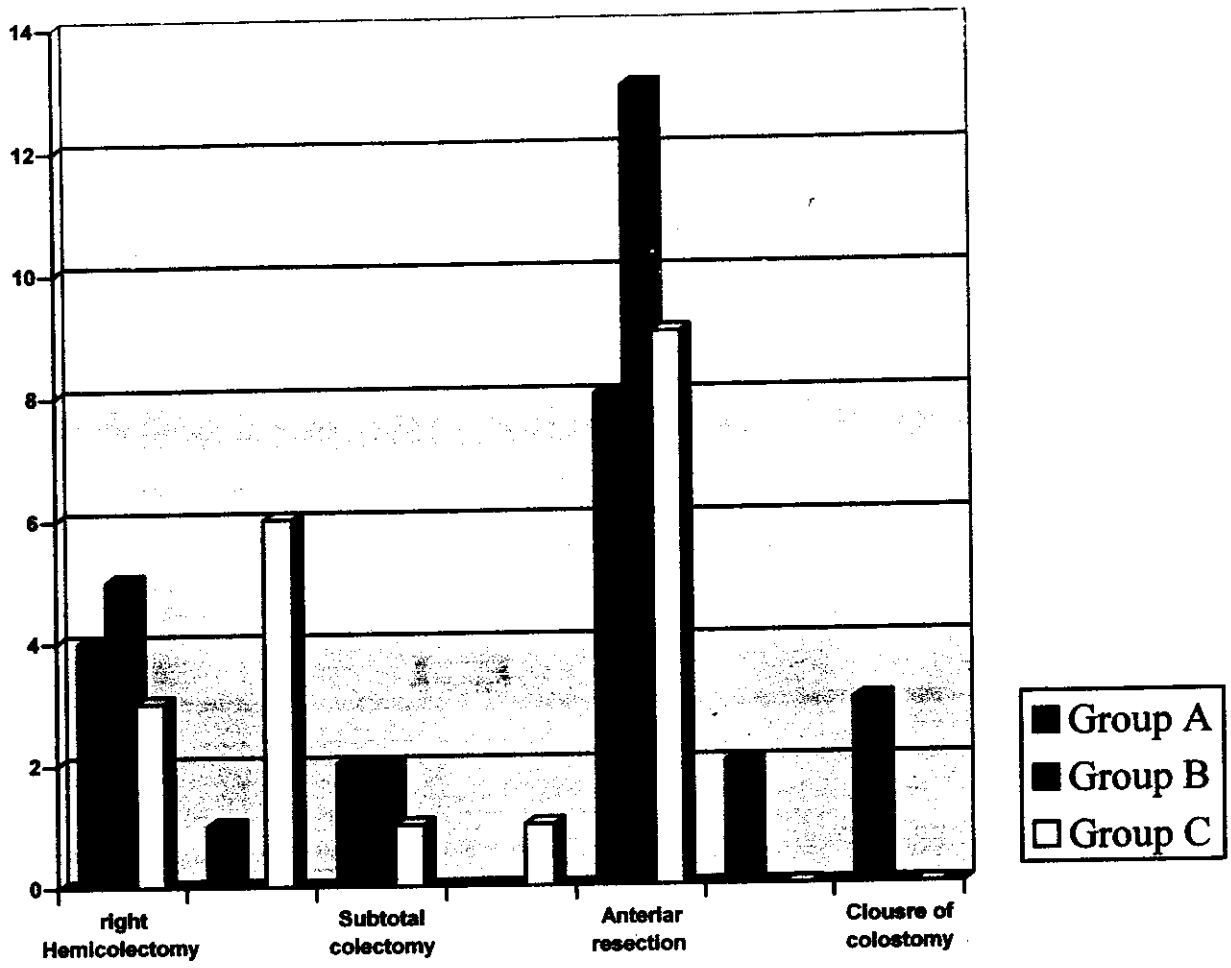
	Average	Mean.
In group A	130	(60-235) minute
In group B	100	(70-215) minute
In group C	120	(80-220) minute

Table(6):

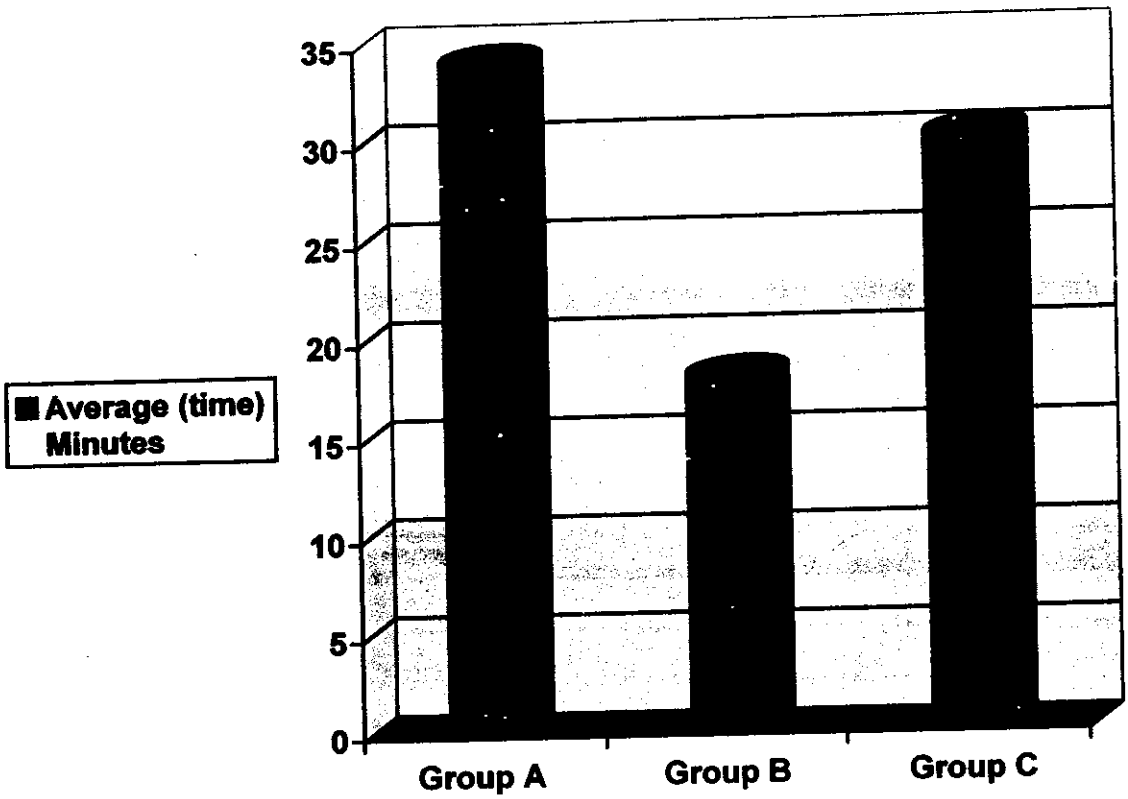
Studied group / Time for operation	(A) Manual no =20	(B) Valerac no=20	(C) Stapler no=20
$\bar{X}$ **Mean value**	123	105	120
± SD	±3.11	±2.63	±2.9

In companion between group A & B the P value < 0.05 (significant) Between group A & C, the P value >0.05 (non significant) between group B & C, the P value <0.05 significant.

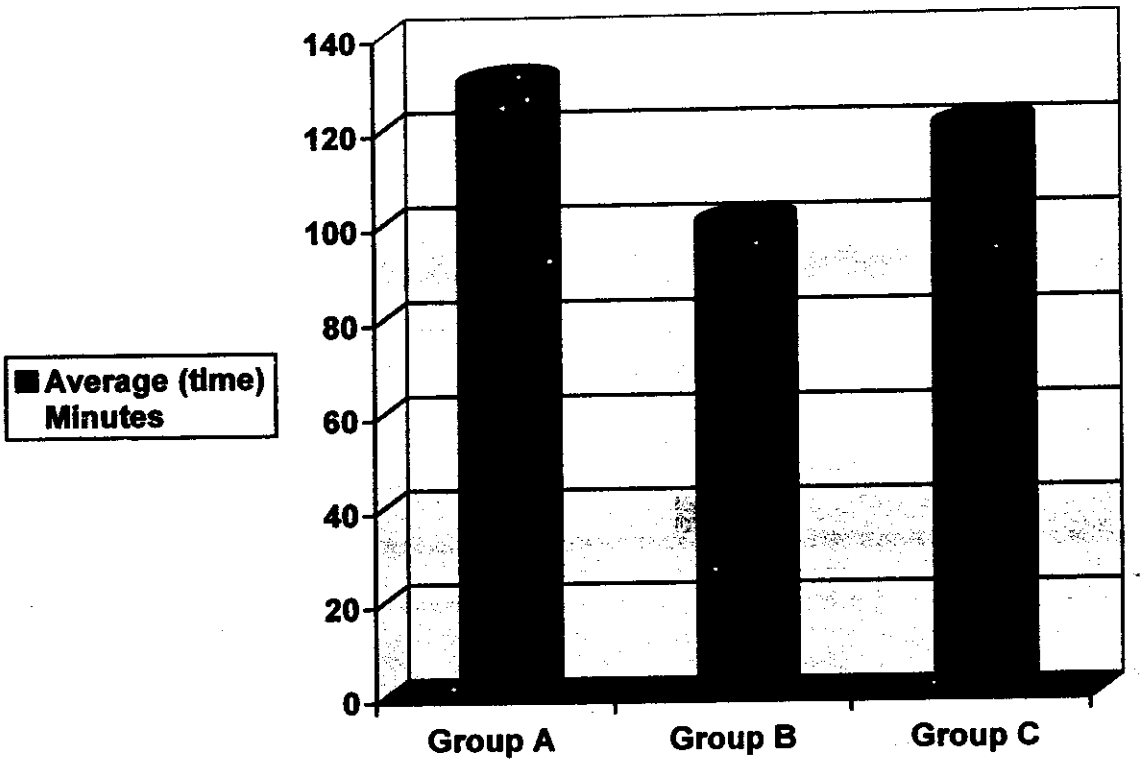
(Fig. 47): Column chart showing type of resection among the studied groups.



(Fig. 48): Cylinder chart showing anastomosis time among the studied groups



(Fig. 49): Cylinder chart showing operation time among the studied groups.



Results of post operative surgery

Table (7): I- Recovery of Bowel function.

(Fig. 50-51)

	Time after operation			P value
	Group A (manual)	Group B valteac	Group C stapler	
1st passage of flatus	3	3	3	>0.05
Clear fluid tolerated successively	4	3	3	>0.05
Full fluid diet tolerated successively	5	4	5	>0.05
low residue diet tolerated successively	6	5	6	>0.05
regular diet tolerated successively	8	7	8	>0.05

P value > 0.05 (non significant)

II- Post-operative complications

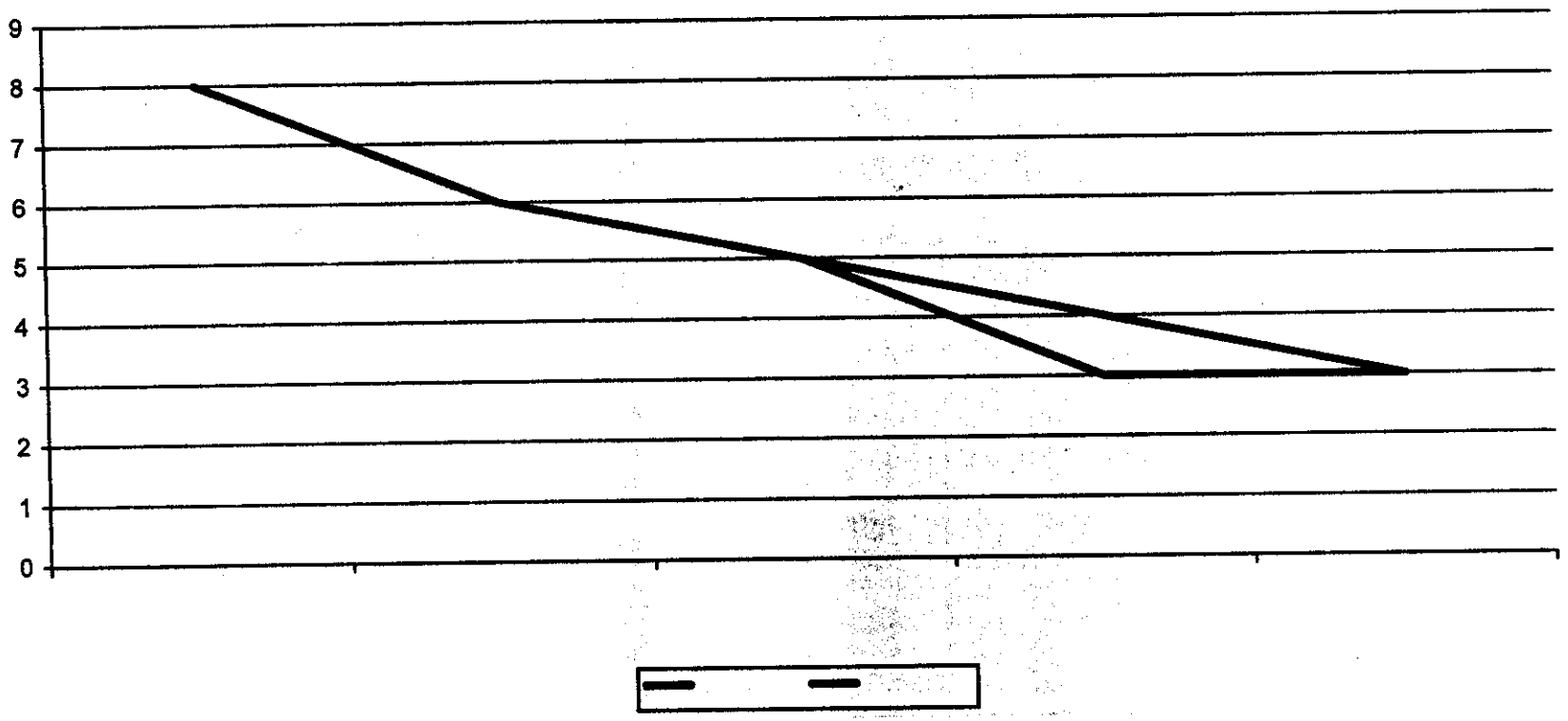
1- **Wound infections** in group (A) 3 patient (15%). In group (B) 2 patient (10%). In group (C) 2 patient (10%).

2- **Cardio- pulmonary complication** No chest infection occurred in the 3 groups of patients, 2 patient in group A (manual) were transferred to the ICU to complete their post-operative treatment due to cardiac problems.

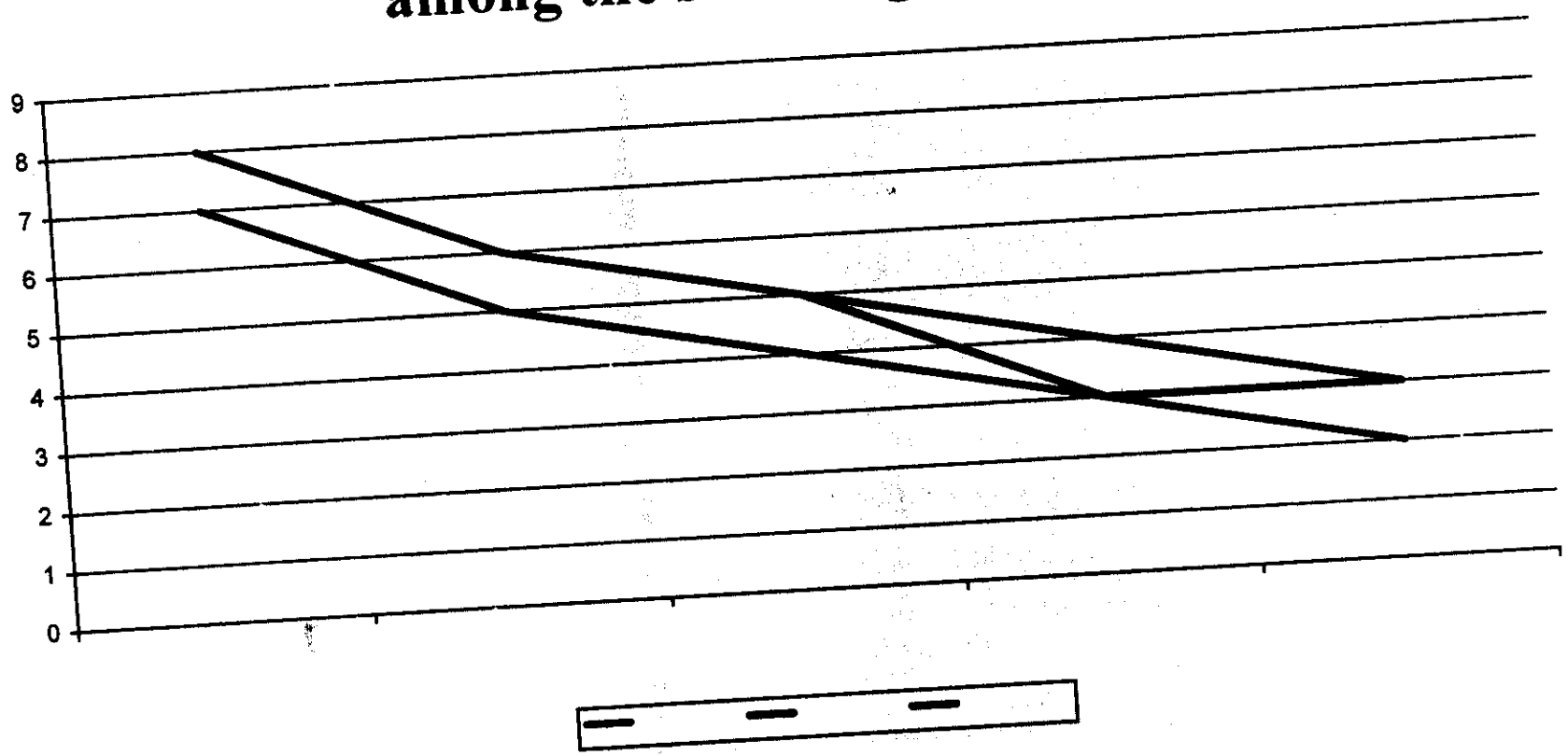
3- **Leakage** in group (A) occur in (1) patient (5%) with colo-colic anastomosis at the 10th post-operative day & it was a minor leak treated conservatively for 2 weeks. In group (B) no leakage occur, in group (C) 1 patient (5%) with colo-colic anastomosis had a minor leak at the 9th postoperative day & treated conservatively for 7 days.

4- **Intestinal obstruction** (ileus) occurs only in 1 (5%) patient in group A which respond to conservative treatment for 5 day.

(Fig. 50): Linear chart showing recovery of bowel function among groups A & C.



(Fig. 51):Linear chart showing recovery of bowel function among the studied groups.



5- **Post-operative Bleeding** occurs in one patient in group C (stapler) 24 hours postoperatively. Drain gives 500 fresh blood, patient was explored, bleeding from mesenteric vessels was secured. The patient completes his post-operative period without complications.

Table(8): Results of post operative complications (Fig. 52)

Group / Complications Related to anastomsis	Group A		Group B		Group C	
	No	%	No	%	No	%
Post operative bleeding	-	-	-	-	1	5
Leakage	1	5	-	-	1	5
Wound infection	3	15	2	10	2	10
Ileus	1	-	-	-	-	-

As regard complications:

between group A & B, the P value < 0.01 (Highly significant)

Between group B & C, the P value <0.01 (Highly significant)

Between group A & C, the P value> 0.05 (non significant)

Hospital stay

Calculated from the day of operation till the day of discharge from the hospital.

In group (A) 7-16 day with an average 9.63 day. In group (B) 7-10 day with an average 8.2 day. In group (C) 7-15 day with an average 9.5 day. (Fig. 53).

Table(9):

Studied group / Hospital Stay	Group A	Group B	Group C
$\bar{X}$	9.6	8.2	9.5
± SD	±0.8	±0.64	±0.8
P	< 0.01		

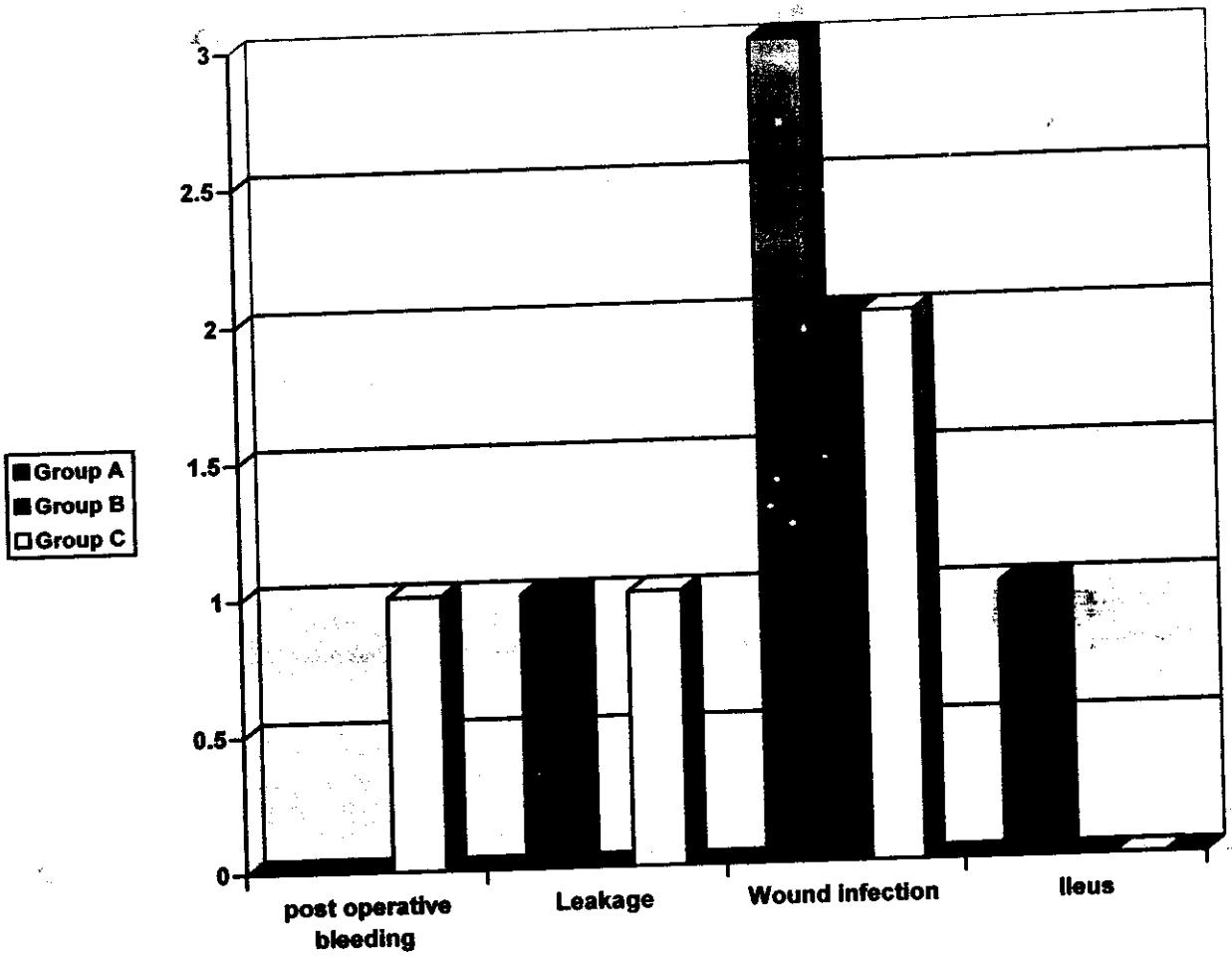
P values are the same between groups A and C.

In comparison between groups A-B with the group C, the P value < 0.01 with is highly significant.

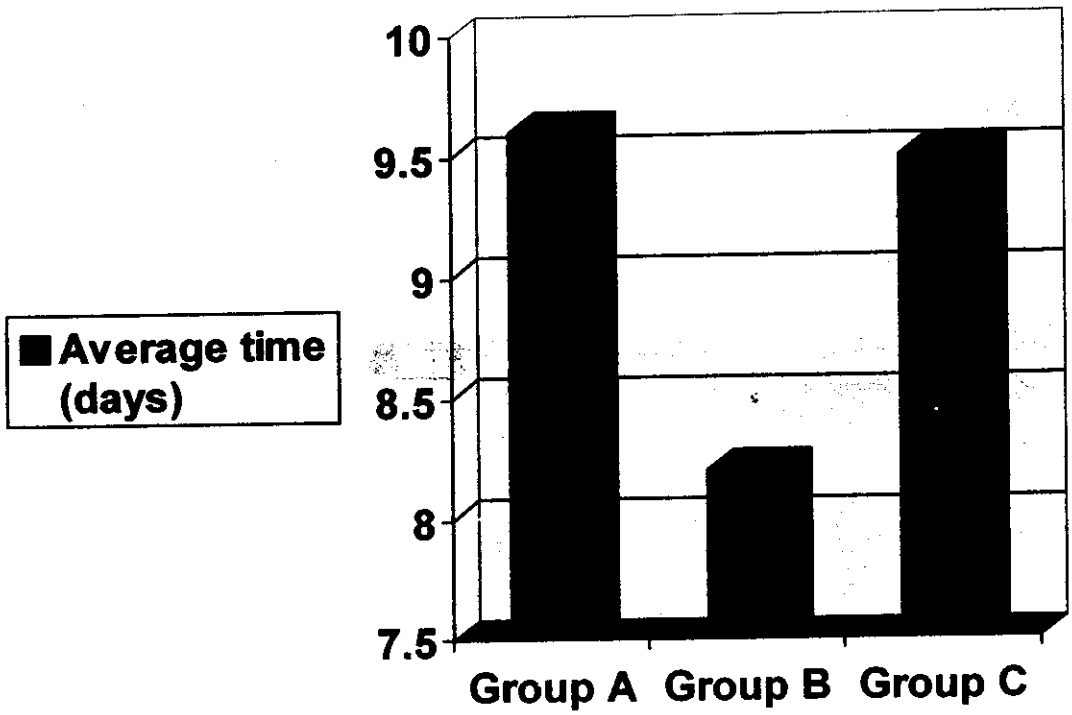
Result of follow up:

Follow up for 6 month at least for each group by endoscopy, some patients have been followed for 17 months. Show no stricture at the anastomotic line in the 3 groups. In group B follow up by X-ray to visualize the BAR fragment which are expelled within 11-19 day post operatively & it's passed unnoticed in stool without discomfort.

(Fig. 52):Column chart showing complications among the studied groups.



(Fig. 53)Column chart showing hospital stay among the studied groups.



Discussion

Discussion

The manual anastomosis has long been accepted as the traditional method of colonic anastomosis, the stapling method has been developed to overcome the problems which have been encountered specially in low colorectal anastomosis. The BAR has been sought as a method that help to over come the hazards and difficulties of the previous 2 methods specially in high risk patient with multiple anastomosis.

The three techniques of anastomosis has been evaluated in a prospective randomized study including 60 patients divided into three groups (A,B and C), each has 20 patients.

In group A difficulty was found in three cases due to very thick edematous bowel wall, so cutting of the bowl wall occur when application of suture material or inversion of the mucosa.

In the group B (BAR) insertion of the BAR into colonic lumen accompanied with some difficulties related to the size of BAR ring or may be associated with mucosal or submucosal tear. This occurred in two cases. The tear was over sewn with interrupted sutures. These difficulties could be avoided by proper training and the proper choice of the size of the BAR.

These difficulties are similar to those reported by ***Choi et al., 1998***, ***Pahlman et al, 1997 and Forde et al, 1993,*** but in that previous studies there is failed randomization in these patients. i.e. the anastomosis done by suture technique instead of the BAR anastomosis in complicated cases.

A different results reported by ***Chua, 1993***, who stated that "no complications or problems associated with Valtrac device during surgery", which is most probably due to his study conducted in elective patient only not including emergency or obstructed cases.

In group C difficult was found in one case in very low colorectal anastomosis as regard the application of TA stapler due to huge mass in rectum and very narrow pelvis, these difficult also reported by ***B.J. Moran 2000***.

In the present study, the operation time for group (A) was 123 minutes and with BAR group (B) was 105 minutes, this shows reduction in operation time with the BAR Group.

Pahlman et al, 1997 reported that, the operation time was 155 minutes for BAR group versus 150 minutes in suture group. Chua, 1993 reported that the operation time was 3 hours (average) for BAR group. Polglase et al, 1993 reported that operation time for BAR was 133 minutes.

In stapler group C the operative time was 120 min. ***Seow – choen 1994*** reported the operative time was 80 min. which it's most probably due to difficult cases present in the present study.

In this study, there is no significant difference between the manual and stapler group. But there is a reduction in operative time between valterac group & other group.

The time used by the surgeons to complete the anastomosis which is recorded in the 3 techniques and is statistically compared. A statistically significant difference was found between the time required to complete the BAR, manual and stapling anasotmosis (18 minutes for

BAR, 34 minutes for manual group and 30 minutes for stapler group), this means that the BAR anastomosis is relatively less time consuming, a factor which may be needed in certain circumstances as emergency and in performing multiple anastomosis.

Anastomosis time in the present study by BAR is nearly similar to that reported by Masato et al, 1999 (21 minutes), Diana et al, 1999 (18 minutes), Konishi et al, 1995 (15.2 minutes) and Forde et al, 1993 (22 minutes).

First bowel movement was started 1-2 days in the BAR group, 2-4 days in staples group and also 2-4 days in manual suture group. The average length of time for return of bowel function was not significantly different.

Fansiler et al, 1994 reported that the average length of time for return of bowel function was not significantly different between BAR (4.3 days) and sutured (5.8 days).

Wang et al, 1996 reported that no significant difference in return of bowel function in both techniques (manual and BAR group).

Seow-choen, 1994 reported that no significant difference in return of bowel function between BAR & stapler groups.

In the present study, the BAR fragments are expelled within 11 to 16 days, a period which is enough for anastomosis to heal completely.

A much longer time are taken till fragmentation of the BAR as reported by: Cusso et al, 2000 who stated that the time was (16^{th} to 21^{st} day) and by Masato et al, 1999 who stated that the time was (18^{th} day) in enterocolic or enterorectal anastomosis, and (20^{th} day) in colocolic or colorectal anastomosis (average).

Hans et al., 1999, reported that fragmentation occur on the 14th post operative day, and ***Walfish et al, 1993*** stated that fragmentation occur 2.5 week post operatively.

Both are similar to the present study in which fragmentation of the BAR occur between (11th and 16th).

The BAR fragments were passed unnoticed with stool with no discomfort. None of the patient were aware of passing the BAR fragments, which is confirmed by plain X-ray.

Chua, 1993 and Tiede et al, 1998 both reported similar results.

Wang et al, 1996 has different results since 7 patients were aware of the passage of BAR fragments.

Also Forde et al, 1993 reported that one patient experienced rectal burning sensation on passing the BAR fragments and in one patient the BAR fragments was visible in his (previous) colostomy appliance.

Wound infection was noticed in 5 patients, 3 (15%) in group A, 2 (10%) in group B, 2 (10%) in group C similar result also reported by Masato et al, 1999 and Chua, 1993. Polglase et al, 1993 reported also similar results.

As regard intestinal obstruction non of BAR group or stapler group showed this complication. One case in group (A) developed ileus. The case was managed by gastrointestinal suction and fluid replacement for 4 days with a satisfactory response.

No obstruction was observed in our study in group B (BAR) and this observation was similar to that of Kurek et al, 2000 and Chua, 1993.

Raynauds et al, 1998 stated that bowel obstruction occur in one case in BAR group.

Seow-Choen, 1994 reported that no intestinal obstruction or prolonged ileus occur in his study between stapler & BAR group.

- in the present study, Postoperative leakage observed in one case in manual group & one in stapler group. No leak in BAR group.
- In manual group, postoperative leak occur on the 10th postoperative day & it was a minor leak. In group C occur on the 9th post operative day both respond well to conservative treatment.

This also reported by ***Kurek et al, 2000, Forde et al, 1993 Seow Choen, 1994, Fansiler et al, 1994***, all stated that no leak was observed post operatively in the BAR patients & stapler group.

A different results reported by ***Cusso et al, 2000*** leakage rate was (2%) in the BAR group, ***Di Castro et al, 1998*** the leakage rate was (2.5%) in the BAR group, ***Pahlman et al., 1997*** leakage rate was (4%) in the BAR group.

No anastomotic bleeding occur in our study in the BAR patients or stapler group this similar to that reported by ***Debus et al., 1999***.

Different results reported by ***Thiede et al, 1998*** the rate of bleeding was (0.18%) in the BAR group, and ***Pahlman et al, 1997*** the bleeding rate was (2%) in the BAR patients but with ***Soew-Choen, 1994,*** No anastomatic bleeding both in BAR & stapler group similar to our result.

No postoperative mortality in our study. This similar to that reported by ***Debus et al, 1999*** and ***Soew-Choen 1994*** they reported no mortality occur post operatively.

A different results reported by ***Massi et al, 1998*** the mortality was (2.4%) in BAR group, and ***Pahlman et al, 1997*** reported that the death

rate was (6%) in BAR group. The cause of death may be due to associated cardiac, pulmonary or renal disease.

The present study shows that the period of hospitalization was 8.2 days in average for BAR group, 9.6 days in average for manual group and 9.5 days for stapler group, it shows reduction in hospital stay in the BAR group.

Hospitalization time was 10.3 days for the BAR patients as reported by ***Bandettini et al, 1999***.

Di castro et al, 1998 reported that the hospital stay was 11.5 days for the BAR patients.

Pahlman et al, 1993 stated that the hospitalization time was 9 days for BAR groups, 9 days for suture group. ***Seow – choen,1994*** stated that hospitalization time was 8 days for BAR group & 10 days for stapler group.

After surgery all patients were followed up and were examined by colonscopy six moths after surgery no clinical problem connected with bowel anastomosis was found.

Our results are similar to those reported by ***Konishi et al, 1995***, and ***Vogel et al, 1993***, who stated that there is no any anastomotic stricture in there study.

Different results reported by ***Di Castro et al, 1998*** the stricture rate was (1%) for BAR group, ***Pahlman et al, 1997*** was (2%) and ***Seow Choen, 1994*** stricture rate was 15% in stapler group.

Summary and Conclusion

The interest in the result from comparisons between hand sewn, stapling & valterac in colorectal anastomosis has been reflected in the progressive increase in the number of clinical trials.

Manual anastomosis the oldest & the traditional method for anastomosis in comparison to other methods.

From our study we found that BAR provides an effective anastomosing method: it gives a completely inverted, non ischaemic anastomosis, without additional residual foreign bodies. It shortens operating time and its technique seems to be easy to learn and to perform. Complications and mortality are not increased even in case of multiple anastomosis. Also it is considered to be safe to preform colonc anastomosis in emergency cases limited to the intraperitoneal colon.

Also the study represents that the stapling technique is a reliable method for performing a colonic anastomosis in a safe & expeditious manner.

However, the hand sewing anastomosis depends intrinsically on the abilily of the surgeon, since their exacution requires appropriate introduction of the needle via the layers of the colon, uniform spacing between passages of the mucosa, in stapling or valter anastomosis device perform these procedure in a uniform and automatic manner. Evidence was found insufficient to demonstrate superiority of the stapling method over hand sewing, independent of the level of colorectal anastomosis.

In low colorectal anastomosis stapler is more expensive, manual anastomosis is more difficult but BAR is now the method of choice.