



ESTABLISHING A CLINICAL AND THERAPEUTIC MODEL TO PREDICT SUCCESSFUL EARLY RE-INTERVENTION IN SEVERELY COMPLICATED LAPAROTOMY AT THE LUBUMBASHI UNIVERSITY HOSPITALS, IN THE DEMOCRATIC REPUBLIC OF CONGO.

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ABSTRACT

Introduction

A major abdominal surgery is mainly the surgical operation during which the cavity of the abdomen is opened and is designed as "coeliotomy" and most frequently "laparotomy". Despite the occurrence of non invasive investigations and the introduction of laparoscopic surgery, in many Third World countries, laparotomy still occupies an important place in the management of surgical patients as diagnostic or treatment tool. In the same manner, post laparotomy complications, despite careful planning and safe surgical technique remain common and have high outcomes risk even at the most skilled and experienced hands in our environment. However it has been shown that early recognition of a postoperative complication that need relaparotomy and a perfect performance of this second laparotomy guarantee the best prognosis.

This study was aiming to develop an accurate and affordable clinic-therapeutic model that allows an early the decision-making process and to propose a related cost effective relaparotomy technique in the similar conditions of medical practice

Methods

This was a prospective analytic cohort study of surgical patients undergoing relaparotomy at the tertiary Hospitals of Lubumbashi: the University clinics of Lubumbashi and the Jackson Sendwe hospital of reference of Lubumbashi (DRC) between 1st January 2012 and 31st December 2015. All patients who had laparotomy during the same the concerned hospitals and in the referring were studied, a total of 304 patients in two groups (with or without relaparotomy). Social demographic factors, data relating to the initial laparotomy, the outcomes after the initial laparotomy, the surgical teams' impact were recorded until patient's discharge (or death). The use of univariate and multivariate analysis with logistic regression of dependent and independent variables has allow to build up a clinic-therapeutic model to predict the need for relaparotomy and the way to perform an effective re laparotomy

Results

In this prospective study, the total amount of patients operated by laparotomy was 304 whose 204 discharged in due time (81,58%, : Group N), and 56 had a re laparotomy (18,42% : Group P). The hospital relaparotomy incidence was 22, 37%. Ages distribution ran from seven months to 83 years in group P with mean age at 34,6 ± 19 years and from 5 years to 68 years. in group N with mean age at 25 ± 14 years.

BY combining analysis of parameters of the two groups, more than 8 variables revealed statistically significant to predict a re-laparotomy after logistic regression were conducted by two separate team: 5 dependent variables as post laparotomy manifestations (sensation from the patient of not feeling well, increasing abdomen perimeter of more than 1cm every 12 hours, high heart beat despite fluid or blood replacement, pour urine out put and permanent dirty surgical site or drainage orifice) and 3 prelaparotomy parameters or independent factors (extreme age: below five or beyond 60 years; referral from outside Lubumbashi city; poor condition at the initial laparotomy due to financial difficulties to fulfill operation fee, patient's co-morbidity ap an ASA grade>I, an emergency laparotomy, or non qualified principal operator)

The logistic regression model was statistically significant, $\chi^2 (6) = 259.2$, $p < 0.0001$. The model explained 96.1% (Nagelkerke R²) of the variance in re-laparotomy and correctly classified 98.7.0% of cases. Sensitivity was 96.2%, specificity was 99.2%, positive predictive value was 96.2% and negative predictive value was 99.2%. Of the six predictor variables only four were statistically significant: Ad>2/d, Finance, Co-morbid condition and GenFeel (as shown in the below). ADgt2d had 976077 times higher odds to undergo re-laparotomy than non-ADgt2d individuals. Increasing the financial capacity and co morbidity was associated with a reduction in likelihood of re-laparotomy but increase in GenFeel and Referrals was associated with a increase in the likelihood of re laparotomy

All re-laparotomies (100%) were done on demand and were not planned from the initial laparotomy. The proposed relaparotomy procedure infers from comparison between uncomplicated and complicated original laparotomies and the observation suggesting that after the first relaparotomy any further relaparotomy should be avoided being not cost-effective..

Conclusion

We have established a clinical and therapeutic model using only locally and affordable diagnostic tools to predict the need for relaparotomy in patients with complicated post major abdominal surgery. An inferred relaparotomy is also presented. It is the hope that both the model and the relaparomy technique will be adopted and get validated by surgical teams working in the similar conditions of service. More research works are still requested in the similar aedas to increase the statistical data

Keywords: Laparotomy complications, Relaparotomy decision , Clinical model, Relaparotomy procedure, Lubumbashi University Hospitals, DR Congo.

INTRODUCTION

It is of the common knowledge that, with an estimated 234 million annually performed operations, surgery constitutes a great integral part of global health care, exceeding by far child birth yearly volume and reported in 2012 by the World Bank, as representing 11% of entire disease burden, evaluated almost at 164 million disability adjusted life years.

Approximately a quarter of this burden is comprising of major abdominal surgeries and that often open the cavity of the abdomen, then designed as “coeliotomy” and most frequently “laparotomy”. Despite the occurrence of non invasive investigations and the introduction of laparoscopic surgery, in many Third-World countries, laparotomy still occupies an important role in the management of surgical patients, as diagnostic or treatment tool. At Lusaka University Teaching Hospital, surgical audits conducted by years 2010 showed an average yearly 9430 surgical operations of which 13% major cases and of these 40% are emergency laparotomies making it a big burden on the surgical practice at UTH.[1]

Although laparotomies prevent the loss of many lives and relieve from many morbid conditions, they are still associated with high risk of complications and death. Data suggests that at least half of all surgical complications are avoidable. The peri operative death is estimated In industrialized countries at 0.4 to 0.8% and a rate of major complications of 3 to 17%.. In our environment a prospective study on relaparotomies at UTH showed a mortality of 40% at the first relaparotomy and of 68% of mortalities after first laporatomies [2] Thus surgical care and its complications represent a substantial burden of disease worthy of attention from the public health community world wide.[1, 3].

In post laparotomy complication needing re-intervention, it has been shown that early recognition and a perfect performance of this second laparotomy (first relaparotomy) do guaranty of better prognosis.[4,5].

A very interesting post operative complications was established in 1992 by Clavien and Dindo Its importance is based on the type of therapy needed to correct the complication. See annex [1]

But as underlined by many authors [4, 5, 6, 7, 8] the decision to re-operate is usually challenging for many reasons: lack of frank and specific peritoneal symptoms or signs in a patient under high catabolic body response, avoidance of re-operation in a critically ill patient or reluctance to recognize proof of failure of the initial laparotomy. Thus, there is no consensus for whom to re-operate or not. Two approaches exist about the decision [9, 10, 11, 12]: the planned relaparotomy (PR) and the on-demand relaparotomy (OD). In the first approach (PR) all major severe intra-abdominal surgeries are taken back every 48 hours to theatre until the source get in under control. With the second approach, OD, patients are treated expectantly and only those with signs of unresolved intra-abdominal complication are subjected to relaparotomy. This last approach was that done in this study for logistical and ethical considerations. In the department, the planned approach was usually only performed for packed severe liver laceration for which a second look was done 48 hours for removal of the pack. In this circumstance, a temporary abdominal was closure done.

Though international and continental literature, studies related to post laparotomy surgical complications do exist as well as subsequent relaparotomy to treat them. Studies to develop clinical and therapeutic models for effective relaparotomy are rare worldwide, and extremely rare in Africa. We found only one study from the South Africa[5] during last ten years and that was for intra-abdominal sepsis following appendicitis and not for after laparotomy of various aetiologies and circumstances.

At the tertiary hospitals of Lubumbashi and at their related district public health institutions, major abdominal surgeries are still carried out by laparotomy, as laparoscopic surgery is still at its beginnings

The main objective of this study was to construct a clinical therapeutic model that will assist clinicians working under the similar conditions to predict the need of effective relaparotomy and the way to perform this re-intervention.

Specific objective were to :

- identifying patients undergoing laparotomy and re-laparotomy at the settings
- establish among the participants a group discharged without relaparotomy (group N) and another that needed relaparotomy (group P)
- determine preoperative, intra-operative and postoperative associate factors in both groups
- seek signification of the associate factors between the two groups
- determine the predictable parameters of a relaparotomy
- construct the model by logistic regression analysis with the most specific clinical ad therapeutic parameters
- Give report of result of performed relaparotomies

PATIENTS AND METHODS

This was a prospective and analytic cohort study carried out between 1st January 2012 to 31st December 2013, at the tertiary Lubumbashi hospitals, the general Hospital of reference Jackson Sendwe (GHJS) and the University Clinics of Lubumbashi (CUL) in the Democratic Republic of Congo (DRC). The GHJS and the CUL are both located in the Lubumbashi, the capital city of former Katanga province and provide surgical care to Lubumbashi citizen but also to urban districts and surrounding rural population. The agreement to conduct the study was obtained by the biomedical ethics committee of the University of Lubumbashi (UNILU) and the administrative approvals of the health institutions.

The study included all patients who underwent laparotomy or relaparotomy in the two settings and admitted either directly or

indirectly as referral from another urban or rural hospital. Participants were gradually introduced in two groups. Group N for patients discharged without re-intervention and Group P for those had a relaparotomy because of early post operative surgical complication.

For each group following associate factors were recorded: before, during and after the laparotomy. The Social-demographical data included age, sex, residential with regard to Lubumbashi city and the patient's source surgery fee. The clinical features considered the patient's general status (co morbidity and ASA grade), the type of laparotomy (emergency or planned), the causes or reasons of laparotomy, the type of incision, the intra-operative findings, the nature of the surgery: excision or not of plain or hollow organ, bowel anastomosis or not, one layer or layer by layer bowel suturing, quality of peritoneal toilet, type of possible peritoneal drainage and the qualification of the team surgeon. The early outcomes post laparotomy (alert symptoms or signs for relaparotomy or not) were analyzed under the patient's malaise (not feeling well), the heart beat/mn, the respiratory rate/mn, the progressive abdomen distension measured at the umbilical level, the existence or not of a diffuse abdominal tender, a rebound tenderness, the amount or recorded urine output the surgical wound or drainage. Baseline laboratory results were also recorded mainly in patients with co-morbidity. Patients were followed with these parameters until their discharge, dead or relaparotomy on demand. Only patients with suggestive signs underwent relaparotomy. The technique of this re-intervention was improved by comparison of the two groups.

The Statistical analysis of data first evaluated the parameters in the two groups: size, age distribution, sex distribution, mean, and then calculated the signification of the associate factors by comparing them in the two groups by the X^2 tests using Pearson's χ^2 test in acceptable sample size and Fisher's exact test elsewhere.

The statistic model predicting the need of the relaparotomy considered factors with high specificity and of high clinical relevance. Our factors were analyzed for logistic regression and by two teams who used three methods: the probability or RL method, the Wald method and the backward stepwise conditional method to predict the need of re-laparotomy with a statistical significance of $p < 0.05$. The gotten data were utilized to generate a receiver operating curve (ROC) to search true-positive and false-positive rate known as sensitivity against 1- specificity. For these statistical data analysis it was used the SPSS info version 21?

To advice a relaparotomy technique or procedure comparisons were made between the procedures carried out in the two study groups with preference given to techniques related to Group N and the departmental experience as well as the review of the literature.

RESULTS

Study period and settings, hospital incidence of the relaparotomy, study groups and pre laparotomy patterns.

From 1st January 2012 to 31st December 2013, 304 patients underwent laparotomy in one the two targeted referral hospitals (the CUL and the HGS) for various presented abdominal conditions. The two groups of the cohort comprised in the first (N group): 248 patients (81,58%) discharged in due time without complications (or after complications that did not require relaparotomy) and in the second (P group) 56 patients (18,42%) who necessitated 68 relaparotomies for early Clavien grade III surgical complications. The hospital incidence of the relaparotomy of this study was 22,37%, indicating that the re-intervention used to occur every five laparotomies.

In the P group, there were more males than females with a sex ratio of 2 males for 1 female; the youngest relaparotomised was 7 days old, the eldest 83 years old and the mean age was 34,6 +/-19 years. In the N group, there were also more males than females but with sex ratio lesser than in the P Group; the mean age for the N Group was 25+/-14 years. The average duration for the patient to reach the referral hospital depended on the patient's residence. It was an almost 48 hour-delay from the initial manifestation to the time of arrival at the referral hospital for the whole cohort. The P group had proportionally more referred patients than the N group coming from locations far away from the tertiary hospitals (65, 12 %). Because of lack of generalized social scheme coverage to health care, the financial feasibility for laparotomy to happen in right time and correct conditions was weaker in case the family alone had to afford the operating theatre fee. At this regard, the P Group was composed with the following theatre fee providers : family: 64%, civil servant: 16%, UNLU staff:13% and staff from private company : 7%

With regard to preoperative clinical features, it was noted the following. There were proportionally more patients with co-morbidity and ASA grade superior to grade II in P Group, respectively 43,43% and 41, 48%) than in N group with co-morbidity (less than 20%) and only 10 % of ASA grade above II. Although complications could be noted at expert hands (39%), the majority of them followed unqualified medical practitioners' and even no medical doctors' surgery (61%). The initial laparotomy was done mainly as an emergency one in the P group (51/56 or 9.07%).

The initial laparotomy characteristics

The midline incision was the most frequently done mainly in N Group followed by oblique and mixed or combine incisions. The reasons for performing laparotomy (intra-operative findings) were almost the same in the two groups with

predominance of intra-abdominal sepsis (55,37% for P Group) and (68,15 for N Group) followed in P Group by malformation condition (17,86%), intestinal obstruction (16,10%), tumoral condition(7,14%) and haemorrhage (3,57. The recorded procedures varied with the condition. Simple adhesiolysis and simple band excision were noted mainly in N Group. There were more intestinal resections than plain visceral excisions. Constructed intestinal anastomosis proportionally involved more large bowel than small bowel in P Group (50% in P Group and 30% in N Group). To construct intestinal anastomosis the suturing technique was done in two or more layers more in P Group (60%) than in N Group where proportionally one layer extra-mucosa suturing prevailed (70%). The peritoneal toilet was or absent or of poor quality mainly in P Group. The same in this group quality adequate drainage was hardly found (absence of suction drainage and no gravity drainage). After septic surgery, one layer closure was mainly found in N Group (72%) in which some laparotomies remained temporally open (10%)

The postoperative complications and need of relaparotomy

The post laparotomy alarming symptoms or signs were less seen or absent in N group while they ranged as follows in the P group (see table 1): six general signs or symptoms: 1/ Not feeling well sensation : fatigue, malaise 2/ Raised Temperature or fever 3/ Raised Heart beat/minute : tachycardia 4/Raised respiratory rate/minute : tachypnea, polypnea 5/ Pallor (eyelid mucosa, palmary and plantar aspects) ; Five signs from patient's observation: 1/Increasing abdominal distension measured at the umbilical level every 12 hours 2/ Diffuse abdominal tenderness 3/ Rebound tenderness 4/ Hourly urine output < 50mls 5/ Hourly nasogastric tube output>50mls Surgical incision or drainage wound permanently wet and dirty.

The associate parameters and significance

The distribution of the associate factors into the two groups, the p-value of the differences and the significance of the distribution are shown in Table 1. The 56 Relaparotomies were made only on demand and no one performed as planned. There represented (18.42%) of the patients who necessitated 68 relaparotomies for early Clavien grade III surgical complication. This illustrates the importance of post-laparotomy manifestations that joined to pre and intra operative factors shall help to decide in the need of Relaparotomy to be done as soon as possible to avoid delay in recovery. The subdivisions of this table are the following: the age, expressed in range of means; the gender (number and percentage) M for male and F for female patients; the residence to state as urban patients from Lubumbashi city (urban community of Lubumbashi; the main source of finance to pay operating theatre fee so that the needed laparotomy could be time done as it was explained in methods section (money to pay operation cost or laparotomy cost and money to acquire its related drugs and consumable or anesthetic package; the intra-operative parameters (emergency or planned, patient with co-morbidity or not and his or her ASA classification, positive findings, characteristics of the procedure and laparotomy team leader operator qualification and post laparotomy manifestations: concern of patient of not feeling well, existence of not of the pallor, heart beat, respiratory rate, perimeter of the abdomen,, diffuse abdomen tenderness, a rebound tenderness, existence of a good urine output, functionality of an inserted NGT and the quality of an eventual the dressing of the surgical site and of the possible draining orifice.

The table 1 shows Pre, intra and post initial laparotomy parameters distribution in the two groups and significance

Parameters	Relaparotomy	No Relaparotomy	p-value Significance	
Age years, median (range)	34 (15-53)	25(11-39)	0,006	S
Gender n(%)				
M	38(67.9)	141(56.8)	0.130	NS
F	18(32.1)	107(43.2)		NS
Residence/referral n(%)				
Patients from Lubumbashi	16(28.6)	172(69.4)		
Patients outside Lubumbashi	40(71.4)	76(30.6)	0,002	S
Operating fee sources n(%)				
Family	36(64.3)	88(35.1)		
Civil servant general	9(16.1)	81(32.7)		
UNILU (University)	7(12.5)	76(30.6)		
Private Company staff	4(7.1)	13 (5.2)	0,000	S
Co-morbidity n(%)				
Patients with- Co-morbidity	26 (46.4)	191(77.0)		
Patients without co-morbidity	30(53.6)	57 (23.0)	0,109	NS
Patients ASA Classification ≤ I:	5(8.9)	208 (83.9)	0,000	S
Patients ASA classification>I:	51(91.1)	40 (16.1)	0,006	S
Emergency/planned surgery				

n(%)				
Emergency	51(91.1)	180 (72.6)		
Panned	5(8.9)	68 (27.4)	0,003	S
Surgeon qualification n(%)				
Qualified head surgeon	22 (39.3)	162 (65.3)		
Non qualified chief operator	34 (60.1)	86 (34.7)	0.00	S
Laparotomy performance				
Midline incision n(%)	50(89.3)	220 (88,7)	0,746	NS
Positive findings n (%)	56 (100.0)	248 (100)		NS
Recto-colic anastomosis n (%)	20 (50.0)	5/30 (16.7)	0,033	S
Multilayer intestinal suturing	30 (75.0)	20(18.2)	0,045	S
Quality peritoneal toilet	7 (13.0)	55(22.1)	0.006	S
Quality abdominal drainage	2 (8.1)	10 (20.0)	0.040	S
Quality wall closure /sepsis	5(45.4)	4 (63.1)	0,000	S
Post-laparotomy features				
Malaise (not feeling well)	47(83.9)	9 (4.0)	0.047	S
Heart beat/mn (range)	120 (95-135)	110(80-120)	0.025	S
Respiratory rate (range)	30 (25-40)	25 (20-30)	0.038	S
Increased abdominal distension n(%)	51(91.1)	10(4.0)	0.044	S
Diffuse abdomen tenderness	48 (85.7)	9 (4.0)	0.047	S
Pallor	35(62.5)	20(8.0)	0.128	NS
Rebound tenderness	38 (67.8)	8(3.3)	0.044	S
Poor urine output	44 (78.6)	8 (3.3)	0.038	S
Increased NGT output	33 (58.9)	15 (6.0)	0.102	NS
Wet and dirty dress	34 (60.7)	18 (7.2)	0.116	NS

M: males, F: female, S: specific, NS; non specific, n: number, %: percentage

Table 2: Early post operative clinical symptoms and Signs in initial laparotomy aetiology

Initial laparotomy intra-operative findings>>>>>	Abdomen sepsis (31)	Mechanical intestinal occlusion and tumoral surgery (13)	Surgery for haemorrhage (2)	Laparotomy for various malformative conditions (10)	
Parameters	n (%)	n (%)	n (%)	n (%)	Overall %
1/ Not feeling well sensation : fatigue, malaise	23/31 74,19%	10/13 76,92%	2/2 100,00%	6/10 60,00%	(83,70%)
2/ Raised Temperature, Fever	25/31 80,65%	2/13 15,38%	0/2 0,00%	1/10 10,00%	(32,01%)
3/Raised Heart beat/minute : tachycardia	24/31 77,42%	10/13 76,92%	2/2 100,%	4/10 40,00%	(84,78%)

4/Raised respiratory rate/minute : tachypnea, polypnea	20/31 64,62%	9/13 69,23%	2/2 100,%	2/10 20,%	(77,95%)
5/Pallor (eyelid mucosa, palmar and plantar aspects)	20/31 64,52	3/13 23,08	2/2 100,00	1/10 10,00	(62,53)
6/Increasing abdominal distension measured at the umbilical level every 12 hours	27/31 87,10%	11/13 84,62%	2/2 100,%	6/10 60,%	(90,57%)
7/Diffuse abdominal tenderness	26/31 83,87%	11/13 84,62%	2/2 100,%	2/10 20,%	(84,49%)
8/Rebound tenderness	24/31 77,42%	10/13 76,92%	1/2 50,00%	3/10 30,%	(68,11%)
9/ Hourly urine output < 50mls	22/31 70,97%	8/13 61,54%	2/2 100%	2/10 20,%	(77,49%)
10/Hourly nasogastric tube output>50mls	20/31 64,52%	8/13 61,54%	½ 50%	2/10 20,%	(58,68%)
11/Surgical incision or drainage wound permanently wet and dirty	19/31 61,29%	9/13 69,23%	1/2 50,%	2/10 20,%	(60,17%)

n: number, %: percentage

The statistic analysis for the logistic regress model

For the Regression model all parameters showing high differences and significance were considered for inclusion the regression model seeking to predict the need for an additional laparorotomy or a relaparotomy. As it is shown on the table 1, the variable was either binary (yes or no) or used a discrete number to identify the quantification of the parameter.

In the first method: LR or "r Probability" method, the data were introduced into the software following three steps. At each step are considered the score, the difference (df) and its significance (sig).

Table 3: shows the first method (probability or LR method)

Variables not in the Equation ^a			Score	df	Sig.
Step 1	Variables	f1agerange	4,419	1	,036
		f2referral	8,823	1	,003
		f3finance	11,692	1	,001
		f4ASAggtl	13,063	1	,000
		f5comorbi	1,346	1	,246
		f5urgent	,023	1	,881
		f6findings	3,591	1	,058
		f7operator	6,129	1	,013
		f8genfeel	27,114	1	,000
		f9hbmrnge	5,661	1	,017
		f10rrmrng	2,279	1	,131
		f12datend	35,929	1	,000
		f13rebtend	32,459	1	,000

		f14uoup	10,608	1	,001
		f15pwwd	7,264	1	,007
		Overall Statistics	92,473	15	,000
Step 2	Variables	f1agerange	9,545	1	,002
		f2referral	,000	1	1,000
		f3finance	34,650	1	,000
		f4ASAgrtl	5,690	1	,017
		f5comorbi	1,280	1	,258
		f5urgent	,619	1	,431
		f6findings	1,312	1	,252
		f7operator	34,650	1	,000
		f8genfeel	33,665	1	,000
		f9hbmrnge	2,692	1	,101
		f10rrmrng	7,513	1	,006
		f13rebtend	,000	1	1,000
		f14uoup	4,414	1	,036
		f15pwwd	3,764	1	,052
Step 3	Variables	f1agerange	7,879	1	,005
		f2referral	,258	1	,612
		f4ASAgrtl	3,611	1	,057
		f5comorbi	,000	1	1,000
		f5urgent	,000	1	1,000
		f6findings	13,000	1	,000
		f7operator	3,611	1	,057
		f8genfeel	13,000	1	,000
		f9hbmrnge	3,611	1	,057
		f10rrmrng	,000	1	1,000
		f13rebtend	.	1	.
		f14uoup	7,879	1	,005
		f15pwwd	2,359	1	,125
Step 4	Variables	f1agerange	7,879	1	,005
		f2referral	,258	1	,612
		f4ASAgrtl	3,611	1	,057
		f5comorbi	,000	1	1,000
		f5urgent	,000	1	1,000
		f6findings	13,000	1	,000
		f7operator	3,611	1	,057
		f8genfeel	13,000	1	,000
		f9hbmrnge	3,611	1	,057
		f10rrmrng	,000	1	1,000
		f14uoup	7,879	1	,005
		f15pwwd	2,359	1	,125
		Overall Statistics	13,000	12	,369

a. Residual Chi-Squares are not computed because of redundancies.

Legend for First Method or LR

First step: introduction of the following factors or variable or parameters

f1agerange : factor 1 : age, f2 referral; f3finance: factor 4 finance source for operating fee, f5ASAg: factor 5 ASA classification, f5comorbi: factor 5 co-morbidity, f5urgent: factor 5 (repeated) urgent: factor 5 (repeated) operation done as emergency or not, f6findings: factor 6 intra-operative positive findings or reason of laparotomy, f7operator: factor 7t surgical team leader, f8genfeel: factor 8 general feeling or wellness, f9bmm: factor 9 heart rate or heart beat per minute mean; f10rrmmg: factor 10 respirator rate per minute or mean, f12 datend: factor 12 distended abdomen measured at umbilical level, f13rebtend: factor 13 : rebound tenderness, f14uoup: factor 13 urine output and f15pwwd: permanent wet wound or drainage orifice

At the end of this step, many parameters were still of high signification: age, referral, finance, ASA, operator, co-mortality, general feeling, heart beat, Distended abdominal, rebound tenderness, urine output and wet dress

Second step: the same parameters are introduced. Are still significant : age, finance, ASA, operator, general feeling, respiratory rate, urine output, wet dress.

Third step: Introduction of the same parameters, the following parameters remain significant: age, ASA, findings, general feeling, heart beat, urine output

Fourth step: introduction of the same variables. Remain in the course: age, operator (limit), , general feeling, heart beat and urine output

In summary this first method use four steps with all variable and gives as predictors: age, operator (limited), general feeling, heart beat and urine output at its fourth step

In the second method, data are introduced into to the machine in two steps. The same variables, differences and significations are looked at

Table 4 shows the second method or Wald Method

a. Residual Chi-Squares are not computed because of redundancies.					
			Score	df	Sig.
Step 1	Variables	f1agerange	4,419	1	,036
		f2referral	8,823	1	,003
		f3finance	11,692	1	,001
		f4ASAgrgtI	13,063	1	,000
		f5comorbi	1,346	1	,246
		f5urgent	,023	1	,881
		f6findings	3,591	1	,058
		f7operator	6,129	1	,013
		f8genfeel	27,114	1	,000
		f9hbmrnge	5,661	1	,017
		f10rrmrng	2,279	1	,131
		f12datend	35,929	1	,000
		f13rebtend	32,459	1	,000
		f14uoup	10,608	1	,001
		f15pwwd	7,264	1	,007
Overall Statistics		92,473	15	,000	
Step 2	Variables	f1agerange	9,545	1	,002
		f2referral	,000	1	1,000
		f3finance	34,650	1	,000
		f4ASAgrgtI	5,690	1	,017
		f5comorbi	1,280	1	,258
		f5urgent	,619	1	,431
		f6findings	1,312	1	,252
		f7operator	34,650	1	,000
		f8genfeel	33,665	1	,000
		f9hbmrnge	2,692	1	,101
		f10rrmrng	7,513	1	,006
		f13rebtend	,000	1	1,000
		f14uoup	4,414	1	,036
		f15pwwd	3,764	1	,052

At the end of the first step, the following parameters rare significant : age, referral, finance, ASA , findings (limited), operator, general feeling (undetermined), heart beat, diffuse abdomen tenderness undetermined, rebound tenderness (undetermined), urine output, wet dress

At the end of the step 2 of the second method or WALD method remain significant the following: age, finance, ASA, operator, general feeling, respiratory rate, urine output, permanent wet dress(limited)

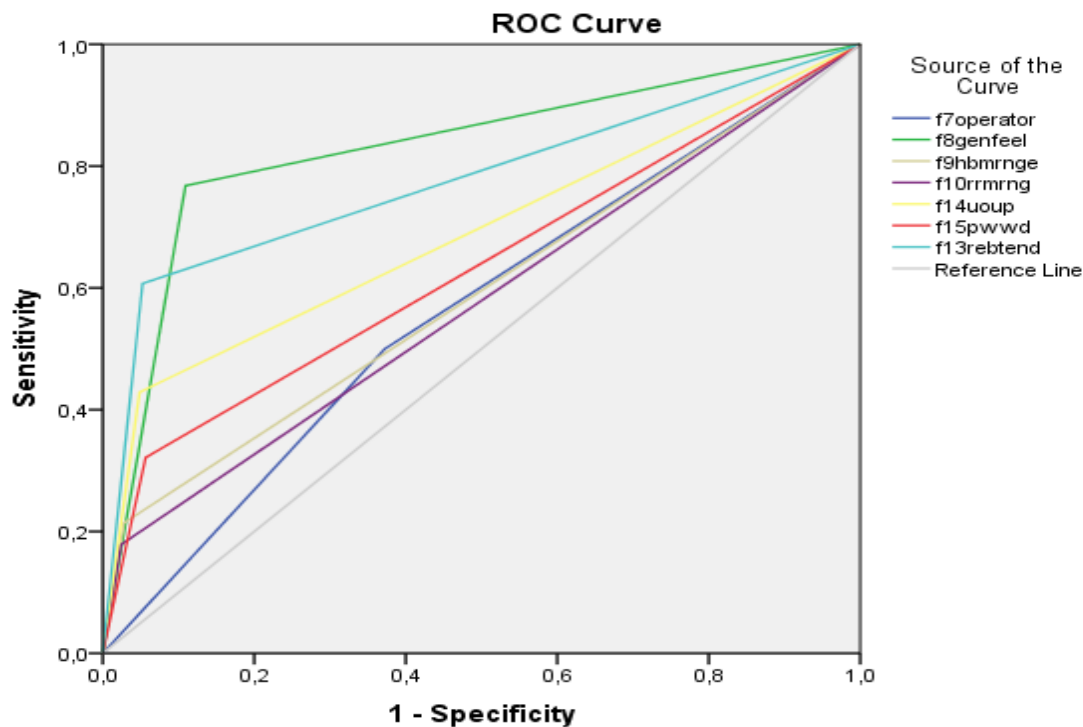
In the third method or forward conditional method, the parameters undergo four steps as in the first method

Table 5: shows the forward conditional method or backward stepwise method

<i>Variables not in the Equation^a</i>			
	Score	df	Sig.

Step 1	Variables	f1agerange	4,419	1	,036
		f2referral	8,823	1	,003
		f3finance	11,692	1	,001
		f4ASAggrgtl	13,063	1	,000
		f5comorbi	1,346	1	,246
		f5urgent	,023	1	,881
		f6findings	3,591	1	,058
		f7operator	6,129	1	,013
		f8genfeel	27,114	1	,000
		f9hbmrange	5,661	1	,017
		f10rrmrng	2,279	1	,131
		f12datend	35,929	1	,000
		f13rebtend	32,459	1	,000
		f14uoup	10,608	1	,001
		f15pwwd	7,264	1	,007
	Overall Statistics		92,473	15	,000
Step 2	Variables	f1agerange	9,545	1	,002
		f2referral	,000	1	1,000
		f3finance	34,650	1	,000
		f4ASAggrgtl	5,690	1	,017
		f5comorbi	1,280	1	,258
		f5urgent	,619	1	,431
		f6findings	1,312	1	,252
		f7operator	34,650	1	,000
		f8genfeel	33,665	1	,000
		f9hbmrange	2,692	1	,101
		f10rrmrng	7,513	1	,006
		f13rebtend	,000	1	1,000
		f14uoup	4,414	1	,036
		f15pwwd	3,764	1	,052
Step 3	Variables	f1agerange	7,879	1	,005
		f2referral	,258	1	,612
		f4ASAggrgtl	3,611	1	,057
		f5comorbi	,000	1	1,000
		f5urgent	,000	1	1,000
		f6findings	13,000	1	,000
		f7operator	3,611	1	,057
		f8genfeel	13,000	1	,000
		f9hbmrange	3,611	1	,057
		f10rrmrng	,000	1	1,000
		f13rebtend	.	1	.
		f14uoup	7,879	1	,005
		f15pwwd	2,359	1	,125
Step 4	Variables	f1agerange	7,879	1	,005
		f2referral	,258	1	,612
		f4ASAggrgtl	3,611	1	,057
		f5comorbi	,000	1	1,000
		f5urgent	,000	1	1,000
		f6findings	13,000	1	,000
		f7operator	3,611	1	,057
		f8genfeel	13,000	1	,000
		f9hbmrange	3,611	1	,057
		f10rrmrng	,000	1	1,000
		f14uoup	7,879	1	,005
		f15pwwd	2,359	1	,125
	Overall Statistics		13,000	12	,369

a. Residual Chi-Squares are not computed because of redundancies.



Diagonal segments are produced by ties.

Figure 2 : ROC CURVE in Wald method

Legend:

f7operator: F7. no qualified surgeon; *f8genfeel*: F8: general sensation of not feeling well; *f9hbmrange*: F9 heart beat per minute; *f10rrmrng*: F10: respiratory rate; *f14uoup*: F14: urine output; *f15pwwd*: F15: surgical wound permanently dirty

At the end of the forward conditional method remain significant the following: ASA (limited), findings (undetermined), general feeling, urine output.

INTERPRETATIONS OF METHODS

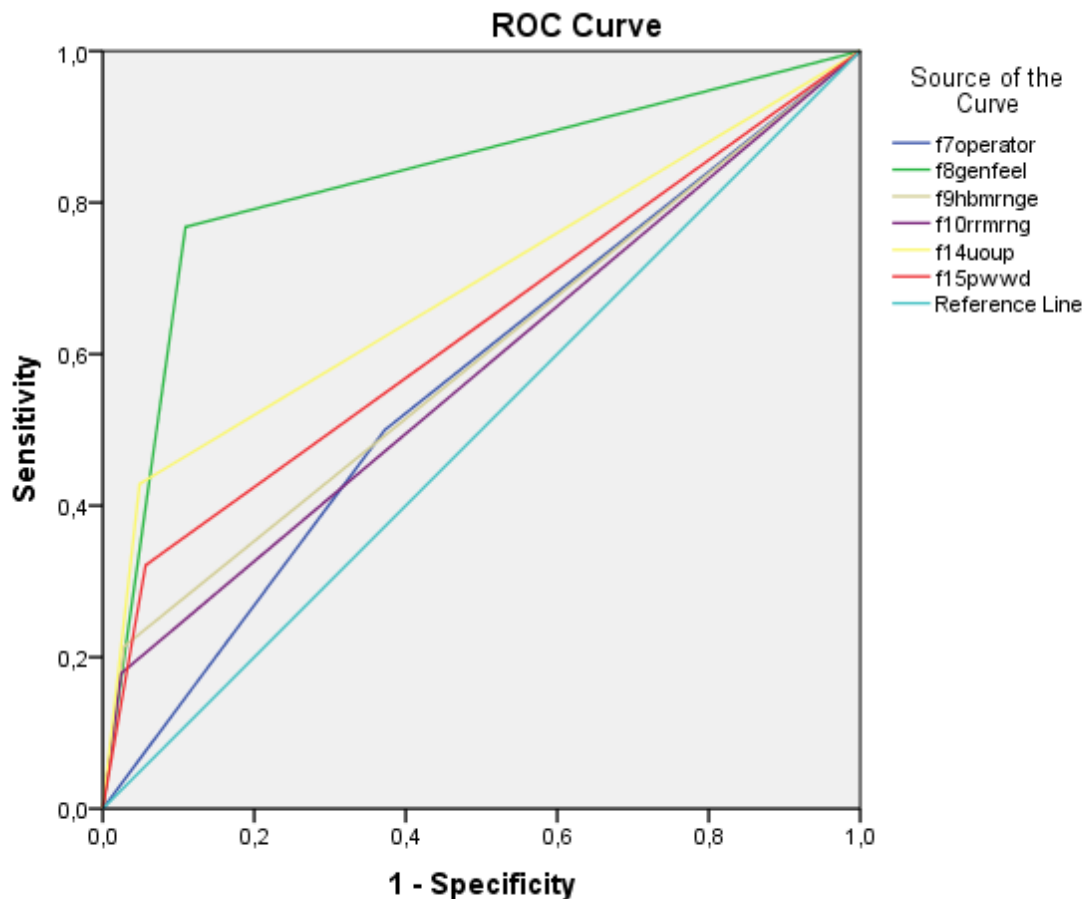
A. ROC CURVE (LR) : FIRST METHOD (LR) or Probability method

NB: The curve of all the adopted predictor factors of the model appear in the Figure 1

B ROC under curve to Wald Method is done in figure 2

Table 6 shows the Area under the curve of LR or Probability method

Area Under the Curve					
Test Result Variable(s)	Area	Std. Error ^a	Asymptotic Sig. ^b	Asymptotic 95% Confidence Interval	
				Lower Bound	Upper Bound
<i>f7operator</i>	,564	,043	,136	,480	,648
<i>f8genfeel</i>	,829	,035	,000	,761	,898
<i>f9hbmrange</i>	,593	,046	,030	,503	,683
<i>f10rrmrng</i>	,577	,046	,071	,488	,666
<i>f14uoup</i>	,690	,045	,000	,602	,778
<i>f15pwwd</i>	,632	,046	,002	,543	,722
The test result variable(s): <i>f7operator</i> , <i>f8genfeel</i> , <i>f9hbmrange</i> , <i>f10rrmrng</i> , <i>f14uoup</i> , <i>f15pwwd</i> has at least one tie between the positive actual state group and the negative actual state group. Statistics may be biased.					
a. Under the non parametric assumption					
b. CURVE OF ROC OF WALD METHOD					



Diagonal segments are produced by ties.

Figure 1 : Curves in LR method

Legend:

f7operator: F7. no qualified surgeon; *f8genfeel*: F8: general sensation of not feeling well; *f9hbmng*: F9 heart beat per minute; *f10rrmng*: F10: respiratory rate; *f14uoup*: F14: urine output; *f15pwwd*: F15: surgical wound permanently dirty

In the fourth Logistic Regression of Results Method done by different team (one step of modified WALD method)

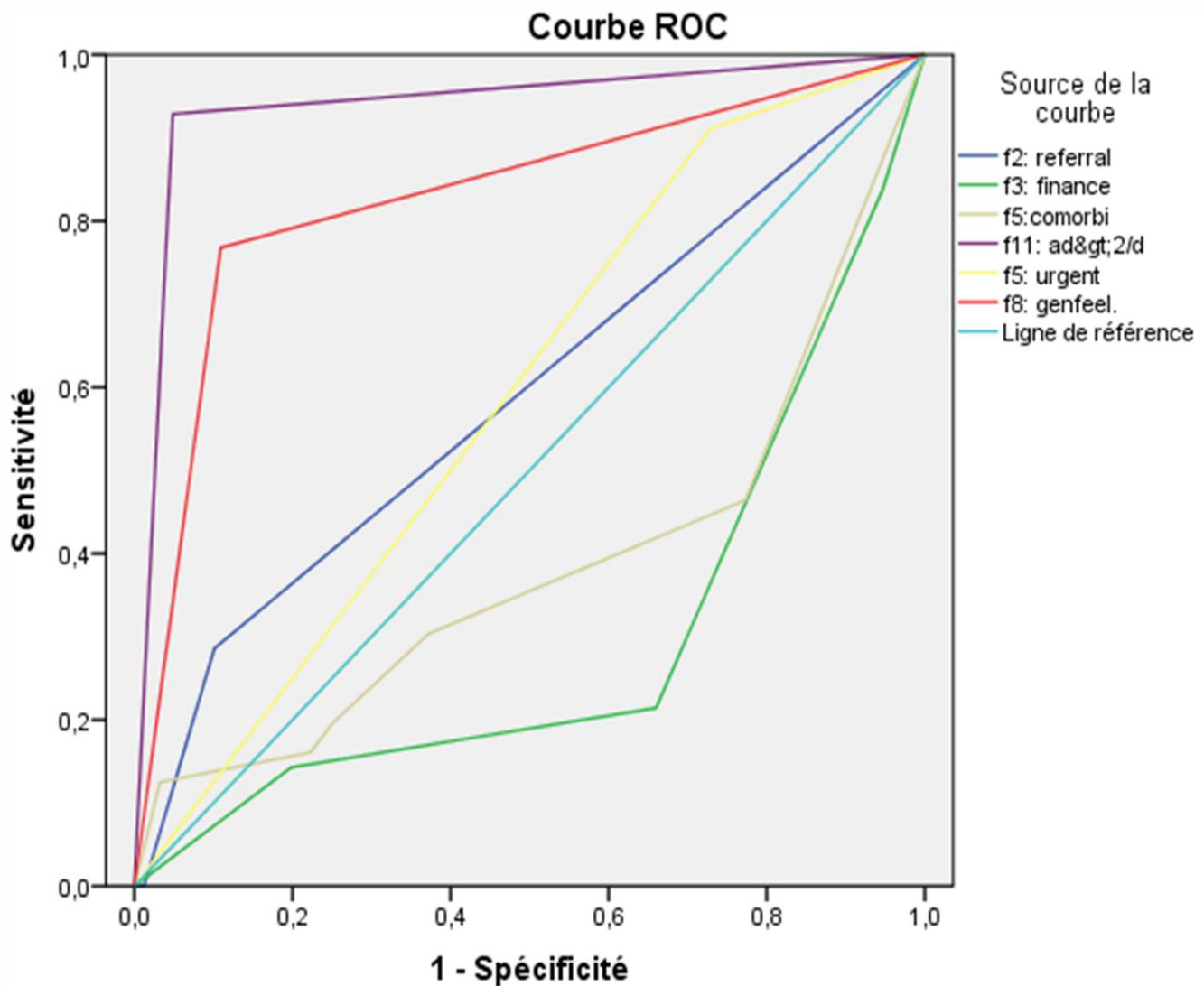
A binomial logistic regression was performed to ascertain the effects of **Ad>2/d**(Increasing abdomen distension measured at the umbilicus level superior to 2cm per day or 1 cm every 12 hours); **referral**; referred or not referred patients, **finance**: financial source of operating theatre cost; **co-morbid** condition: patient with or without co-morbidity; urgent: emergency or planned laparotomy; **genFeel** : sensation of not feeling well or ASA grading above grade I; on the likelihood that participants will undergo relaparotomy.

Table 7 shows the binomial regression done by a different team

Variables in the Equation : AD, Finance, Co-morbidity, General feeling									
		B	S.E.	Wald	df	Sig.	Exp(B)	95% C.I. for EXP(B)	
								Lower	Upper
Step 1 ^a	Ad>2/d	13.791	4.392	9.858	1	.002	976077.233	178.074	5350176741.404
	Referral	.253	1.157	.048	1	.827	1.287	.133	12.429

Finance	-3.213	1.249	6.613	1	.010	.040	.003	.466
Comorbid	-2.513	.984	6.514	1	.011	.081	.012	.558
Urgent	1.606	3.878	.171	1	.679	4.983	.002	9966.741
GenFeel	4.960	1.924	6.647	1	.010	142.656	3.285	6194.572
Constant	.054	4.126	.000	1	.990	1.055		

a. Variable(s) entered on step 1: Ad>2/d, Referral, Finance, Co-morbid, Urgent, GenFeel.



Les segments diagonaux sont générés par des liaisons.

Legend:

Courbe: Curve; Sensitivité: sensitivity; Spécificité: specificity;

Source de la courbe : source of the curve ; Les segments diagonaux sont générés par des liaisons : Diagonal segments are generated by tie.

Ligne de référence : line of reference

This ROC curve shows the validity of the parameter "sensation of not feeling well , the importance of "the abdomen distension" and the delay related to "referral". The three other parameters have less sensitivity and are located below the line of

reference.(co-morbidity, finance and emergency).

After the logistic regression done separately with Wald method using six parameters see table, there was four studentized residual with values of **5.638, 3.365, 2.837 and 5.234** standard deviations, which were removed from the logistic regression analysis.

The logistic regression without independent model predictors showed that 81.5% of cases overall could be correctly classified by simply assuming that all cases were classified as no re-laparotomy.

The logistic regression model was statistically significant, $\chi^2(6) = 259.2$, $p < 0.0001$.

The model explained 96.1% (Nagelkerke R^2) of the variance in re-laparotomy and correctly classified 98.7.0% of cases. Sensitivity was 96.2%, specificity was 99.2%, positive predictive value was 96.2% and negative predictive value was 99.2%. Of the six predictor variables only four were statistically significant: Ad>2/d, Finance, Co-morbid condition and GenFeel (as shown in the below). ADgt2d had 976077 times higher odds to undergo re-laparotomy than non-ADgt2d individuals. Increasing the financial capacity and co morbidity was associated with a reduction in likelihood of re-laparotomy but increase in GenFeel and Referrals was associated with a increase in the likelihood of re laparotomy

The construction of a simplified clinical model which could be utilized

It infers from the following steps

Overview of all statically predictor

On view of this logistic regression analysis by the four methods, the following have been considered as statistically predictor of the need for relaparotomy out of **15 specific factors**:

F2: referral (residence) +

F9: heart beat Hbmn+

F3: finance (operation fee)+

F8: General sensation of malaise++

F4: co-morbidity+

F12: ad or abdomen distension+

F7: operator+

F14: urine output+

F1 Age (extreme)

F15: permanent wet wound dress+

Dependent and independent variables among the parameters

The then above factors, statistically predictors of the need for re-laparotomy, could be part of the Model Equation. To avoid redundancy and seek consistency and feasibility it is worthy to consider the parameters above the line of reference:

Postoperative alarming signs or symptoms (Dependent variables)

- Sensation of not feeling well (permanent malaise or anxiety) (F8)
- Increasing abdomen distension measured at the umbilicus level (F12)
- Tachycardia despite correct liquid or blood supply ranging from 100 to 135 beat/mn (F9)
- Despite these measures poor urine out put (F14)
- Surgical incision or drainage orifice repeatedly wet or dirty(F15)

Pre or intra-operative aggravating parameters (independent variables)

- Delay to tertiary hospital mainly secondary to referral from rural health center
- Poor condition of the initial laparotomy especially because of qualified personnel (F7)
- Patient child below 5 years or elderly beyond 65 years

The power of the factor in the method it was calculated and come to establish as eight above mentioned predicators that may fit in the following usual equation:

$$\log it(p) = -K + aX_1 + bX_2 + cX_3 + dX_4 + eX_5 + fX_6 + gX_7 + hX_8$$

$$\log it ((p) =) \ln\left(\frac{p}{1-p}\right)$$

in which

- K: is a constant numeric value
- a, b, c, d, e, f, g, h are also constant value related respectively X1, X2, X3, X4, X5, X6, X7, X8,
- X1: general feeling of patient (malaise) (F8) that found statistically significant in all modes of analysis that used it (LR method, WALD method, BACKWARD STEPWISE CONDITIONAL method and in the binary logistic regression done by a separate team that used 6 factors only. It has been assessed by yes or no and taken as dependent variable
- X2: heart beat (tachycardia) (F9), that was found statistically significant wherever it was tested except in LR. It has been assessed by a number and a range and considered a dependent variable
- X3: abdomen distension (F12) that was strongly significant where it was tested in the fourth method that stands as Wald method, equally present as specific in all sorts of complications: sepsis, intestinal obstruction, hemoperitoneum and represented a measurable clinical sign
- X4: urine output (F14) that was found statistically significant in the three first methods: LR, Wald and Backward Stepwise Conditional methods and represented a dependent variable
- X5 : Wet surgical incision and drainage orifice (F15) that was found significant in methods 1(LR) and 2 (Wald) constituted an easy to diagnosed dependent variable
- X6 : Referral (F2) that had predictable value in first step of the first method and in the fourth method and could contribute in delaying the operation and also by the of residence
- X7: Operator (quality and experience of the surgical team leader) (F7) that was found statistically significant in the three first methods used: LR, Wald, Stepwise conditional methods and constituted a real public health problem in the third world in general and in the setting of this work in particular
- X8: Age that was found in many methods and consist mainly in the difficulties of diagnosing and treating children and elderly people

Simplified clinical model can statistically be on the following assertions.

A relaparotomy shall be decided and be performed with 95 % probability as soon as possible in the presence of

- **Three** out of five following dependent parameters [(malaise (x1), heart rate>110bpm (x2), increased abdomen distension> 1cm/12 hours (x3), urine output < 50 mls/hour (x4) and surgical wound or drainage orifice repeatedly wet(x5)] and
- **Two** out of three following independent parameters [delayed referral of more than 48hours for emergency laparotomy (x6); poor circumstances of laparotomy (x7) due to co-morbidity or unqualified staff; child under five aged or elderly beyond 65 (x8)]

Relaparotomy results

The procedure

The mean duration between the initial surgery and the relaparotomy was 72 hours ranging from 7 hours (same day) to ten days due to the initial laparotomy site, the effectiveness of the transfer and preoperative preparation, in relationship with the patient, the complication and the ancillary logistics.

At the tertiary university hospitals almost all relaparotomies were performed by qualified and experienced surgeons (76,79%) and to this regard the difference related to the qualification in team surgical leader in was significant with $p = 0,0249$. All relaparotomies were done under general anesthesia with endotracheal intubation and oxygen assistance. Five were initially planned for spinal anesthesia but were converted to general anesthesia.

In comparison with the initial laparotomy. 45 relaparotomies out of 56 were undertaken by midline incision (80%) followed by oblique incisions: 6/56 (.11%) and mixed or combined 6/56 (9%). The total resections of early adhesions or bands, plain visceral and intestines was 12 with predominance of intestinal resections 8/12 (.66.1%). For out of 8 intestinal resections five involving or stomach or duodenum, or small bowels, one step resection was done with end to end or end to side anastomosis performed in the same time (100%). For the three involving the colorectal segment, one on with perforated caecum underwent one step right hemicolon resection with ileotransverse anastomosis and two affecting the descending and the sigmoid colons had Hartmann colostomy as part of damage control operation in severe sepsis with doubtful stumps. Almost all intestinal suturing (90%) mainly during construction of anastomosis was done on interrupted- one-layer extramucosal model with semi-absorbable, or chromic catgut or no absorbable 00 suture if the previous unavailable. A meticulous peritoneal toilet

and copious washing of the cavity with at least 5L of saline was done in 16/20 (80%). Despite its own complications and in case of severely massive sepsis with possible unattended residual pockets of pus a peritoneal drainage was inserted 35/56 (44.1%) mainly by gravity by lack of "Redon-like" drainage system. Mass closure has been achieved in 50/56 (89%). 4/56 (7%) needed parietoplasty and 2/56 (4%) were left partially open.

Postoperatively 20/56 patients (36-%) had a mean stay in intensive care unit of 7 days running from 2 to 18 days.

First relaparotomy outcomes

After the relaparotomy, 12 patients (21.4%) demised and 44 (78.4%) survived with or without complication according to Clavien classification. Out of these 44 patients who survived, 9 (16%) were discharged from hospital without any surgery. The remaining were kept in either for more resuscitation or for possible second relaparotomy

These outcomes are illustrated on table 8 of or Clavien and Dondi Classification

Table 8: Outcomes post 1st relaparotomies: Clavien and Dondiclassification

<i>Post relaparotomy outcomes on Clavien Classification</i>	<i>Effectif (n)</i>	<i>Pourcentage (%)</i>
- <i>Grade I</i>	00	00
- <i>Grade II</i>	09	16,07
- <i>Grade IIIa</i>	08	14,29
- <i>Grade IIIb</i>	08	14,29
- <i>Grade Iva</i>	09	16,07
- <i>Grade IVb</i>	06	10,71
- <i>Grade V</i>	08	14,29
	02	3,57
	08	14,29
	02	3,57
	02	02
	(12)	(21,43)

Table 8: Outcomes post 1st relaparotomies: Clavien and Dondicclassification

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- <i>Grade V</i>	02	3,57
	08	14,29
	02	3,57
	08	14,29
	02	3,57
	02	02
	(12)	(21,43)
<i>Total</i>	56	100,00

As compared to the patients discharged without relaparotomy after the initial laparotomy, only patients with Classification II on Clavien and Dondu could be discharged after relaparotomy.

Factors influencing the relaparotomy outcomes had mainly been represented by the delay before relaparotomy and multi organs failure.

In fact after the 9 patients discharged post relaparotomy, the other 32 needed more care either for purely medical care or for extra peritoneal surgical care

- without or with local or loco regional anesthesia for the complications grade III (8 patients or 14,29%) ; grade IIIa (9 patients 16,07 %) ;
- grade IV (8 patients or 14,29%) ; grade IVa (2 patients or 3,57%) and grade IVb (2 patients or 3,57%)

The 12 post relaparotomy deaths were mainly secondary to multi organs failures and to prolonged delay. All relaparotomised who demised had at least two or more organs or systems failure: circulatory (23.1%), renal(23.1%), respiratory(respiratory (23.4%), hepatic (17.3%) or psychological (13.5%)..

The delay between the surgical complication and the time of relaparotomy played a major role on the post-relaparotomy outcome. More complications and deaths occurred in relaparotomy beyond three days.

Second or further relaparotomy outcomes

The outcomes of the second or further relaparotomy are very poor and do discourage to perform (apart from planned re-intervention as to close or reverse a temporary colostomy or a wall left open to avoid abdomen compartment syndrome or massive sepsis). In this study, first laparotomy outcomes were the following: Six patients among survivors with surgical complications underwent a second relaparotomy. Out of these six, two demised (33.3% %), two discharged (33.3%), two needed prolonged resuscitation

The second relaparotomy mortality was beyond 30% (33.3%) with proportion survivors to deaths of 67/33 while, after the first relaparotomy, survivors to deaths proportion was 79/21. It clearly appears that repeated relaparotomy does not leave more chance to survive.

DISCUSSION

As noted by many authors worldwide surgical complications following major abdominal surgery are challenging and ought to be recognized promptly for the improvement of the outcomes as morbidity and mortality are significant[1,8,13,14] In fact, this recognition is not always easy due to the body response to the abdominal surgical trauma overshadowing classical peritoneal signs [2, 5,]. Hence need of developing clinical model simple, locally realizable to prevent the delay in on

demand approach known as source of in dramatically increased morbidity and mortality as reported by Kong YV et al. [5] and many other authors[12, 15,16,17, 18] about the general consensus on the use of this on demand approach. In our limited resource settings we used the OD approach, the most cost effective one.

Then we need predictors of the relaparotomy in our environment to shorten the delay of controlling the complication source; This is also because our hospital incidence of 22.% compared to that from Mali (13.7: Boré B, on 40 laparotomies 2006), from France (3%: Montravers et al, on 84 cases in 2004), but less than the Niger incidence (28.8, on 160 cases, :Harona Y et al, 2000).

The proposed model constructed during a prospective cohort study with two valid groups and with a logistic regression process carried out by two separate biostatistics teams looks strong. The logistic regression model was statistically significant, $\chi^2(6) = 259.2$, $p < 0.0001$.

The model explained 96.1% (Nagelkerke R^2) of the variance in re-laparotomy and correctly classified 98.7.0% of cases. Sensitivity was 96.2%, specificity was 99.2%, positive predictive value was 96.2% and negative predictive value was 99.2%.

Of the six predictor variables only four were statistically significant: Ad>2/d, Finance, Co-morbid condition and GenFeel (as shown in the below). ADgt2d had 976077 times higher odds to undergo re-laparotomy than non-ADgt2d individuals. Increasing the financial capacity and comorbidity was associated with a reduction in likelihood of re-laparotomy, but increase in GenFeel and Referrals was associated with a increase in the likelihood of re laparotomy

The strength of the predictors are indicated by the logistic regression. Some of them might appeared weak as looked at isolate like finance, co-morbidity, heart beat but the association proposed of three dependent out of 5 and two independent variables out of three confer the solidity to the equation. We hope that our simplified clinical model will be adopted through the decision taking as well as for further researches to confirm its validation

The proposed relaparotomy technique inferring from this study by comparing it in the two groups N and P, but also relating to departmental experience and to literature especially from Springer Science and Business .[20] and Massimo Sartelli M et al [21] has the following focus : a perfect preparation of the patient always weakened by the initial laparotomy; an experienced chief anesthetist to deliver a well dosed anesthesia, general or loco regional with adequate oxygenation; an experienced principal surgeon able to perform an adequate approach, a meticulous intra-abdominal monitoring which may recommend a damage control operation, able to remove all sources of sepsis, to achieve viable and reasonable intestinal anastomosis avoiding leaks, to ensure a real peritoneal toilet, to perform if necessary a functional drainage of the abdominal cavity, to achieve with ripeness of judgment the abdomen wall closure particularly after septic surgery and avoiding creation of abdominal compartmental syndrome.

CONCLUSIONS

Severe postlaparotomy complications requesting an early relaparotomy are frequent in our settings with an average hospital incidence of one re-intervention every five major abdominal surgery. Surgical, anesthetic, nursing and other paramedical teams must be involved to offer the patient the ultimate chance of surviving by an early well conceived relaparotomy. Because planned relaparotomy is not cost effective in our limited resource health facilities, the

on-demand approach is usually adopted. This latter needs a simplified and accurate clinical model to predict the need of relaparotomy and avoid dramatic outcome related to delay re-intervention

The clinico-therapeutic model presented by the surgical Department of surgery, School of Medicine, University of Lubumbashi is a strongly scoring system to precisely predict an effective relaparotomy to be carried out following a methodic and professional procedure.

RECOMMENDATION

Surgical teams working on the similar conditions are invited to apply the clinical model and communicate their results to the department for the validation of the model. The same researchers of the same health facilities are invited to more bigger prospective studies to increase the number and update current study.

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- Assistants' researcher
- Journal Editor in chief and all peer reviewers

Conflicts of interest

Authors declare any conflict of interest in relation to the conception, writing and dissemination of this article

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