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original article

Enhanced recovery after surgery efficacy in an older patients and high-risk population affected by colorectal cancer: a more than 1000 patients experience

M. SCATIZZI[1], F. FEROCI[2], A. ZIRONDA[2], E. LENZI[2], M. BARAGHINI[2], A. GARZI[2], L. ROMOLI[2], T. ZALLA[2], R. GIUDICISSI[2], I. GIANI[2], C. ELBETTI[2], M. FRANCESCHIN[3], S. CANTAFIO[2]

SUMMARY: **Enhanced recovery after surgery efficacy in an older patients and high-risk population affected by colorectal cancer: a more than 1000 patients experience.**

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Aim. *Enhanced recovery after surgery programs aims to standardize care, improving colorectal surgery outcomes. Older patients are a challenge population for these programs. The aim of this manuscript is to explore the effect of application Enhanced recovery after surgery protocol among older patients and high-risk patients undergone colorectal surgery for cancer.*

Method. *Since January 2005, until September 2016, 1189 consecutive patients underwent elective Colorectal Surgery and treated according to our Enhanced recovery after surgery protocol.*

Patients are divided in three groups according to age: Group1 under 69 y-o (control group), Group2 70 to 79 y-o and Group3 over 80 y-o. Primary end point was Time to Readiness to Discharge.

Results. *Median Time to Readiness to Discharge was 4 days (3-30) in Group 1, 5 (3-47) in Group 2 and 5 (3-19) in Group 3. Length of stay in Group 1 had a median length of 6 days (3-58), in Group 2 of 8 days (3-70) and in Group 3 of 8 days (3-53).*

Conclusions. *Once more Enhanced recovery after surgery program has showed its efficacy in colorectal surgery field. Moreover, our experience has underlined the need to concentrate efforts mainly on older and high-risk patients.*

KEY WORDS: Colorectal surgery - Length of stay - Elective surgical procedures - ERAS.

Introduction

In the last decades General Surgery has been revolutionized by several innovations such as mini invasive and laparoscopic surgery (1, 2), mechanical staplers (3) and last but not least Enhanced Recovery After Surgery (ERAS) programs (4).

ERAS was introduced by Professor Henrik Khelet, with the aim "to obtain a comprehensive recovery after any surgical intervention" (5).

Application of ERAS protocols have demonstrated to minimize morbidity by decreasing secondary complications but also being cost-effective in shortening the length of hospital stay (LOS) (6).

In this panorama of innovations and scientific revolutions laparoscopic surgery growth, and in particular its role in minimizing the surgical trauma ha let to be the best ally of ERAS programs in order to achieve a synergic effect on the ERAS items themselves (7).

Older patients have been recently explored as a possible and new field of application and success of ERAS programs, despite some authors assumed they would be unfeasible due to physical impairments or associated comorbidities (8, 9).

Despite incomplete adhesion to ERAS protocols by 100% patients evaluated, its effectiveness has confirmed (10).

[1] Department of General Surgery, "Santa Maria Annunziata" Hospital, Florence, Italy
[2] Department of General and Oncologic Surgery, "Santo Stefano" Hospital, Prato, Italy
[3] "Istituto Clinico San Rocco", Ome (BS), Italy

*Name of the institution were the study was performe*d: Department of General and Oncologic Surgery, Santo Stefano Hospital, Via Suor Niccolina Infermiera, 20, 59100, Prato, Italy

Corresponding author: Rosina Giudicissi, e-mail: giudicissi.rosina@gmail.com

Older patients are those with higher incidence of colorectal tumors but also carriers of a greater incidence of morbidity. Because of this, they need to be considered a target for ERAS protocols more than young and healthy patients.

Aim of our study is to explore the effect of application ERAS protocol among older patients and high-risk patients undergone colorectal surgery for cancer.

Patients and methods

Since January 2005 all consecutive patients underwent elective Colorectal Surgery and treated according to our ERAS protocol (8) are collected in a prospective maintained database.

According to the aim of our study we considered those patients included until September 2016 dividing them in three groups according to age: Group1 under 69 y-o (control group), Group2 between 70 and 79 y-o and Group3 over 80 y-o.

Exclusion criteria were emergency surgery, age less than 18 years, impaired mental status due to inability of giving an informed consent, inability to respect ERAS protocol items as evaluated by a surgeon of our team and pregnancy.

Risk criteria

According to literacy on ERAS, we decided to adopt ASA physical-status classification system (11). ASA≥ III was considered as high risk while ASA I and II were considered as low risk.

Surgical intervention

All procedures were conducted or supervised by three colorectal fellowship-trained surgeons.

Surgical interventions were performed with a standard technique previously described (12).

ERAS protocol

ERAS protocol was conducted according to an experience published by Feroci et al. (8).

Discharge criteria

Discharge was possible from the third postoperative day when patients matched the following criteria: absence of complications, ability to tolerate solid food, passage of first stool, mobilization and preoperative self-support and adequate pain control with oral medication (9, 13).

Measurement

Primary end point was Time to Readiness to Discharge (TRD), defined as the day when a patient is feasible to discharge (9, 13).

As secondary end points we considered length of stay (LOS) as the postoperative hospitalization days, readmissions, morbidity and mortality in the first 30 days after surgery registered during outpatient clinic visit follow up and the adherence to the ERAS program (8).

Parameters were recorded on the hospitalization day, during the stay and during the first 30 postop follow up days.

Statistical analyses

Clinical outcome variables included the LOS, 30-day morbidity and readmission rates.

Univariate analysis was initially performed to assess the relationship between each ERAS intervention with an adherence rate<100% and the outcome variables.

A univariate analysis was performed using the Mann-Whitney U test for continuous variables, and $\chi 2$ was used for categorical variables.

A multivariate analysis using binary logistic regression for categorical variables and linear regression of log transformed continuous variables was performed for all variables with a significant or near significant difference ($p<0.15$) in univariate analysis.

Adherence was calculated as the number of fulfilled interventions/14 (total number of preoperative and perioperative interventions), and patients were divided into four adherence groups: 100 %, 85-95%, 70-80%, and <65% (8).

Each adherence group was compared with the other groups to evaluate differences in clinical outcome variables.

Analyses were performed using the Mann-Whitney U test for continuous variables, and $\chi 2$ was used for categorical variables. For all analyses, p values<0.05 were considered statistically significant, and all tests were two-sided. The results are reported as a median (range) or frequency (percent). Data were analyzed on an intention-to-treat basis. Data

were tabulated in a Microsoft® Excel spreadsheet (Excel for Windows®; Microsoft Corporation, Redmond, Washington, USA) and processed using SPSS 16.0 for Windows® (SPSS, Chicago, Illinois, USA).

Results

This analysis considered an overall number of 1189 patients (584 women, 49.1%), median age 76 y-o (range 30-94 y-o).

Baseline characteristics of this population are described in Table 1. In particular a laparoscopic surgical approach was conducted on 500 patients (42%).

Primary, secondary end-points and postoperative outcomes are shown in Table 2.

TRD had a median of 4 days (3-47), postoperative stay had a median length of 7 days (1-70), readmission rate was 2.4% (29 patients), 30-days morbidity and mortality rate were respectively 38.4% (456 patients) and 2.4% (28 patients) and median ERAS protocol adherence was 70-80%.

Carrying on our results analysis, we divided our population into 3 different groups according to age: Group 1, under 69 y-o, made of 326 patients, Group 2, aged between 70 and 79 y-o, made of 481 patients, and Group 3, aged over 80 y-o, made of 382.

Baseline characteristics are shown in Table 3. Primary, secondary end-points and postoperative outcomes are shown in Table 4.

Laparoscopic surgery in Group 1 was conducted on 210 (64.4%) patients, in Group 2 was conducted on 183 (38%) patients while in Group 3 on 107 (28%) patients. Penetration of laparoscopic surgery between Group 3 patients was statistically significant lower than Group 1 patients ($p<0.001$). No statistically significant differences were seen between Group 1 and 2 and between Group 2 and 3.

Median TRD was 4 days (3-30) in Group 1, 5 (3-47) in Group 2 and 5 (3-19) in Group 3.

LOS in Group 1 had a median length of 6 days (3-58), in Group 2 of 8 days (3-70) and in Group 3 of 8 days (3-53).

Readmission rate was 3% (10 patients) in Group 1, 2.3% (11 patients) in Group 2 and 2.1% (8 patients) in Group 3.

30-day morbidity and mortality rate were respectively 25.5% and 0.6% (83 and 2 patients) in Group 1, 38.7% and 1.7% (186 and 8 patients) in Group 2,49% and 4.7% (187 and 18 patients) in Group 3.

Median adherence to ERAS protocol was 85-95% in Group 1 while in Group 2 and 3 was <65%.

TRD, LOS and 30-day morbidity were statistically significant lower in Group 1 patients than in Group 2 and 3 ($p<0.001$). No differences were seen between Group 2 and Group 3.

No differences were recorded on readmissions and mortality.

Median adherence was statistically significant higher in Group 1 patients than in Group 2 and 3 ($p<0.001$).

Cause the lack of data and studies on older patients, we focused on Group 3. Furthermore, we focused on high risk older patients, since they are the majority of this group (269 ASA III and IV on 382 patients) and represent an important category in our reality, due to epidemiological reasons.

Within this group the importance of adherence to the ERAS protocol on primary and secondary outcomes was explored using as cut-off the adherence median value of 70-80%.

Results are shown in Table 5.

Between Group 3 high risk patients adherence <70-80%, TRD was 5 days (3-19), LOS 9 days (3-43), readmissions rate 2-8% (6 patients), 30-days morbidity rate was 56.5% (122 patients) and 30-days mortality rate was 5.1% (11 patients).

In Group 3 high risk patients adherence ≥70-80%, TRD was 3 days (3-19), LOS 6 days (3-21), readmissions 0, 30-day morbidity rate was 22.6% (12 patients) and 30-days mortality rate was 1.9% (1 patients).

TRD, LOS, readmissions and morbidity were statistically significant lower in patients with higher adherence ($p<0.001$).

No statistically significant difference was recorded on 30-day mortality ($p=0.186$).

Discussion

This work is the largest single center experience in literacy on the evaluation of ERAS program efficacy on colorectal cancer surgery patients.

TABLE 1 - BASELINE CHARACTERISTICS AND PERIOPERATIVE RESULTS.

Patients (n = 1189)	
Age (y)	76 (30-94)
Sex ratio (M:F)	605:584 (50.9:49.1)
ASA	
I	128 (10.8)
II	452 (38)
III	587 (43.4)
IV	22 (1.9)
I-II vs III-IV	508 vs 609
Comorbidity	793 (66.7)
Pulmonary	190 (16)
Cardiovascular	665 (55.9)
Renal	54 (4.5)
Diabetes	172 (14.5)
Liver	47 (4)
Pathology site	
Colon	541 (45.5)
Sigmoid-rectum junction	430 (36.2)
Rectum	218 (18.3)
Operation	
Right hemicolectomy	438 (36.8)
Transverse resection	20 (1.7)
Left flexure resection	25 (2.1)
Left hemicolectomy	284 (23.9)
Sigmoid resection	35 (2.9)
Anterior resection	260 (21.9)
Trans-anal resection	6 (0.5)
Hartmann operation	87 (7.3)
Miles	19 (1.6)
Total colectomy	15 (1.3)
Laparoscopic operation and/or transverse incisions	
Laparoscopic	500 (42)
Open	539 (49.9)
Conversion	96 (8)
Ileostomy	68 (5.7)
Drain positioning	902 (75.9)
Intraoperative complications	77 (6.5)
Spleen rupture	21 (1.8)
Other hemorrhages	10 (1)
No tumor findings	1 (0.1)
Colonic injury	1 (0.1)

Data are medians with range in parentheses for continuous variables.
Data are numbers with percentages in parentheses for categorial variables.
ASA indicates American Society of Anesthesiologists; *F:* female; *M*: male
ERAS indicates Enhanced Recovery After Surgery

The statistical power represented by the 1189 patients examined, as well as the temporal extension of almost 10 years, are the main strength elements of this work.

Furthermorefor a better understanding of the cases in question, we would like to point out the elevated median age and the elevated rate of High Risk patients (ASA III and IV), elements that should

TABLE 2 - PRIMARY, SECONDARY END-POINTS AND POSTOPERATIVE OUTCOMES.

TRD	4 (3-47)
LOS	7 (3-70)
Readmissions	29 (2.4)
Morbidity	456 (38.4)
Mortality	28 (2.4)
Adherence rate to ERAS Median <65% 70-80% 85-95% 100%	 70-80% (0-100%) 587 (49.4) 192 (16.4) 248 (20.9) 162 (13.6)
Mobilization POD	1 (0-30)
First bowel movement POD	2 (0-13)
First flatus POD	2 (0-40)
Liquid diet toleration POD	1 (0-42)
Solid diet toleration POD	3 (0-47)
Drain removal POD	3 (0-30)
Bladder catheter removal	2 (0-29)
NGT tube reinsertion	128 (10.8)
Bladder catheter reinsertion	95 (8)
Analgesic administration (oral or iv) POD	3 (0-40)
Reintervention	58 (4.9)

Data are medians with range in parentheses for continuous variables.
Data are numbers with percentages in parentheses for categorial variables.
NGT indicates nasogastric tube; *POD*, postoperative day

be considered for an objective analysis of the results.

Moreover, it is important to evidence a 42% of laparoscopic approach rate, similar to those reported by other experiences in literature (14).
According to our aims, we evaluated TRD as primary endpoint.

We obtained an overall value of 4 days, analogue to the one reported by others works, such as Braga et al. (9) and Santiago et al. (14).

This value it was statistically significant higher in patients belonging to Group 2 and 3. This difference is probably due to the baseline characteristics differences between the 3 groups examined, particularly due to the statistically significant incrementof High Risk patients in Group 2 and 3.

Then mean LOS, as secondary end point, has been observed to be 7 days, respectively 6 in Group 1, 8 in Group 2 and Group 3.

Difference between Group 1 and the two other Groups has been demonstrated statically significant.

This value appears to be higher than what is reported in ERAS program literature (15, 16) but lesser than the ones reported for standard care in colorectal surgery (17).

Another time this difference into the three groups could be related to the differences in the baseline characteristics as age, comorbidities and ERAS protocol adherence rate.

Burdened by absolute importance is the straight statistically significant difference between TRD and LOS.

TRD, already introduced and evaluated by other authors on literacy, Braga et al. (9), Fiore et al. (18), was used as a toolto standardize the effectiveness of ERAS programs according to precise shared criteria.

Santiago et al. (14) referenced to ERAS estimated discharge, Feroci et al. (10), already in 2013, defined precise discharge criteria and point out the

TABLE 3 - BASELINE CHARACTERISTICS.

Age (y)	≤69 N=326	70-79 N=481	≥80 N=382	p 1vs2	p 1vs3	p 2vs3
Sex ratio (M-F)	194:132	236:245	175:207	p<0.001*	p<0.001*	p<0.001*
ASA grade						
I	73 (22.4)	37 [7.7]	18 [4.7]	p<0.001*	p<0.001*	p<0.001*
II	174 (53.4)	183 [38]	95 [24.9]			
III	76 (23.3)	249 [51.8]	262 [68.6]			
IV	3 (0.9)	12 [2.5]	7 [1.8]			
I-II vs III-IV	247 vs 79	220 vs 261	113 vs 269	p<0.001*	p<0.001*	p<0.001*
Comorbidity	162 [49.7]	327 [68]	304 [79.6]	p<0.001*	p<0.001*	p=0.001
Pulmonary	48 [15]	76 [15.8]	66 [17.3]	p=1.000	p=1.000	p=1.000
Cardiovascular	115 [35.3]	278 [57.8]	272 [71.2]	p<0.001*	p<0.001*	p<0.001*
Renal	9 [2.8]	22 [4.6]	23 [6]	p=0.645	p=0.113	p=0.972
Diabetes	32 [9.8]	88 [18.3]	52 [13.6]	p=0.002	p=0.445	p=0.136
Liver	10 [3.1]	22 [4.6]	15 [3.9]	p=0.800	p=1.000	p=1.000
Pathology site				p=0.002	p<0.001*	p=0.081
Colon	116 [35.6]	219 [45.5]	206 [53.9]			
Sigmoid-rectum junction	145[44.5]	167 [34.7]	118 [30.9]			
Rectum	65 [19.9]	95 [19.8]	58 [15.2]			
Operation				p=1.000	p=0.219	p=0.435
Right hemicolectomy	84 [25.8]	183 (15.4) [38]	171 [44.8]			
Transverse resection	7 [2.1]	5 (0.4) [1]	8 [2.1]			
Left flexure resection	5 [1.5]	12 [2.5]	8 [2.1]			
Left hemicolectomy	131 [40.2]	93 [19.8]	60 [15.7]			
Sigmoid resection	1 [0.3]	15 [3.1]	19 [5]			
Anterior resection	85 [26.1]	121 [25.2]	54 [14.1]			
Trans-anal resection	0 (0)	1 [0.2]	5 [1.3]			
Hartmann operation	6 [1.8]	38 [7.9]	43 [11.3]			
Miles	5 [1.5]	9 [1.9]	5 [1.3]			
Total colectomy	2 [0.6]	4 [0.8]	9 [2.4]			
Laparoscopic operation and/or transverse incisions				p=0.010	p<0.001*	p=0.002
Laparoscopic			107 [28]			
Open	210 [64.4]	183 [38]	243 [63.6]			
Conversion	103 [31.6]	247 [51.4]	32 [8.4]			
Ileostomy	13 [4]	51 [10.6]	9 [2.4]			
Drain positioning	39 [12]	20 [4.2]	286 [74.9]	p<0.001*	p<0.001*	p=0.750
	247 [75.8]	369 [76.7]		p=1.000	p=1.000	p=1.000
Intraoperative complications				p=0.691	p=0.548	p=1.000
Spleen rupture	12	35	30			
Other hemorrhages	2	8	11			
No tumor findings	2	4	4			
Colonic injury	1	0	0			
	1	0	0			

Data are medians with range in parentheses for continuos variables.
Data are numbers with percentages in parentheses for categorial variables.
ASA indicates American Society of Anesthesiologists; *F:* female; *M*: male
ERAS indicates Enhanced Recovery After Surgery

TABLE 4 - PRIMARY, SECONDARY END-POINTS AND POSTOPERATIVE OUTCOMES.

Age (y)	≤69 N=326	70-79 N=481	≥80 N=382	p 1 vs 2	p 1 vs 3	p 2 vs 3
TRD	4 (3-30)	5 (3-47)	5 (3-19)	p<0.001*	p<0.001*	p=1.000
LOS	6 (3-58)	8 (3-70)	8 (3-53)	p<0.001*	p<0.001*	p=0.663
Readmissions	10 (3)	11 (2.3)	8 (2.1)	p=1.000	p=1.000	p=1.000
Morbidity	83 (25.5)	186 (38.7)	187 (49)	p<0.001*	p<0.001*	p=0.008
Mortality	2 (0.6)	8 (1.7)	18 (4.7)	p=1.000	p=0.001	p=0.010
ERAS adherence rate <65% 70-80% 85-95% 100%	85-95% (0-100%) 106 (32.5) 43 (13.2) 98 (30.1) 79 (24.2)	<65% (0-100%) 257 (53.4) 80 (16.6) 92 (19.1) 52 (10.8)	<65% (0-100%) 224 (58.6) 69 (18.1) 58 (15.2) 31 (8.1)	p<0.001*	p<0.001*	p=0.170
Drain removal POD	3 (0-30)	4 (0-24)	4 (0-14)	p=1.000	p=0.816	p=0.226
Bladder catheter removal	1 (0-22)	2 (0-29)	2 (0-11)	p=0.001	p=0.001	p=1.000
NGT tube reinsertion	24 (7.4)	59 (12.3)	45 (11.8)	p=0.008	p=0.002	p=1.000
Bladder catheter reinsertion	14 (4.3)	42 (8.7)	39 (10.2)	p=0.029	p=0.004	p=1.000
Analgesic administration (oral or iv) POD	4 (0-17)	3 (0-25)	3 (0-40)	p=0.002	p=0.024	p=1.000
Reintervention	12 [3.7]	16 [3.3]	30 [7.9]	p=1.000	p=0.060	p=0.086

Data are medians with range in parentheses for continuos variables.
Data are numbers with percentages in parentheses for categorial variables.
NGT indicates nasogastric tube; *POD*, postoperative day

TABLE 5 - GROUP 3 HIGH RISK PATIENTS: PRIMARY, SECONDARY END-POINTS AND POSTOPERATIVE OUTCOMES ACCORDING TO A CUT OFF ERAS ADHERENCE OF 70-80%.

	adherence <70-80% N=216	adherence ≥70-80% N=53	p 1vs2
TRD	5 (3-19)	3 (3-19)	p<0.001*
LOS	9 (3-43)	6 (3-21)	p<0.001*
Readmissions	6 (2.8)	0 (0)	p<0.001*
Morbidity medical morbidity surgical morbidity	122 (56.5) 79 (36.6) 57 (26.4)	12 (22.6) 7 (13.2) 6 (11.3)	p<0.001* p<0.001* p=0.236
Mortality	11 (5.1)	1 (1.9)	p=0.186

Data are medians with range in parentheses for continuos variables.
Data are numbers with percentages in parentheses for categorial variables.

problem of a delayed hospital discharge for older patients linked to economic or social-care reasons.

Conversely, LOS represent the objective number of stay, that could be influenced by others factors then surgical outcome.

Differences on these parameters represent a challenge and could be ascribe, like already pointed out by some authors to medical and social reasons (10, 14).

Particularly, analysing baseline characteristics of our population, emerges the elevated median age

and the elevated number of comorbidities and High-Risk patients as possible causes of these discrepancy between these two parameters.

As further secondary endpoints, readmission rate and mortality rate were both 2.4%, with no statistically significant differences between the three groups. Mortality rate was lower than it was reported for traditional postoperative care in European units (up to 3.4%) (19, 20) and analogue (12) or lower (21) too then other ERAS program experiences.

Readmission rate has been demonstrated as good as reported in traditional care (22) but significant lower than reported in several ERAS programs experiences (23-32).

About mortality, even if no statistically significant difference was point out, an unfavourable trend linked to age could be underlined, with an in increment from 0.6% in Group 1 up to 4.7% in Group 3.

Instead median morbidity rate, equal to 38.4 overall, results statistically significant different in the three groups examined, realistically due to the same differences on baseline characteristics underline before.

Median morbidity rate recorded was 38.4%: this value is similar to traditional care in Europe (from 35% to 38.3%) (19, 20, 33), but higher then reported in some ERAS program experiences (14,8 to 26.7) (13, 33). This could be due to the elevated median age. In fact, looking only at Group 1, the morbidity rate recorded, 25%, was lower, and in line with ERAS program experiences (13, 33).

Median morbidity rate could be related also to the differences between TRD and LOS: extension of the stay could be contributed to evidence promptly and to resolve eventual problems in the immediately postoperative days.

Finally, adherence to ERAS protocol, interesting object of discussion in numerous recent works, has been on average of 70-80%, with a statistically significant difference between Group 1 and the others.

On literacy, an adherence <65% has been demonstrated to be the only important cut off with a significant impact on outcome. This adherence, reported for Group 2 and 3 in our experience, is for certainly, a parameter able to modify our results.

We also analyse in depth Group 3, particularly High-Risk patients, to confirm the importance of the adherence to the ERAS protocol. We use an adherence of 70-80% like cut off to create two groups.

The results pointed out that an adherence greater than 70-80% enable to reduce TRD and LOS also in an older patients, High Risk population.

On the contrary, this adherence it's not linked to a decrease in morbidity, mortality and readmission rate.

Overall low adherence to ERAS protocol in older patients, as demonstrated before, could be related to the pathophysiology of older patients, but also to prudery of the hospital staff to insist on the importance of a correct adherence to all the items of the Protocol.

Not last, it's important the incomplete preoperative information and formation of the patients and of its family about all the operative path.

The overcoming of these difficulties, could be possible with the creation of dedicated figures of reference, dedicated to pre and post operative management of the patients, and also with a critic review of the ERAS protocol items, specifically of the most important, and with the creation of specific tool for older patients and High-Risk patients.

Conclusion

Once more ERAS program has showed its efficacy in colorectal surgery field. Moreover, our experience has underlined the need to concentrate efforts mainly on elderly and high-risk patients.

Human rights statement and informed consent

All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1964 and later versions. Informed consent was obtained from all patients before surgical resections.

Disclosures and conflict of interest statements

All Authors declare they have no conflicts of interest.

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