Title

Introducing the Surgical Therapeutic Index in trauma surgery; an assessment tool for the benefits and risks of operative fracture treatment

Running title

Introducing the Surgical Therapeutic Index in Trauma

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Disclaimer

None

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Abstract

Background

The surgical therapeutic index has been described as an indicator of benefits and risks of surgical treatment. The index is calculated by dividing the cure rate of an operative treatment by the complication rate. This study introduces the STI in trauma surgery by comparing the indices for surgical Plate Fixation (PF) and IntraMedullary Fixation (IMF) of Displaced Midshaft Clavicle Fractures (DMCF).

Methods

In a, previously reported, randomized controlled fashion 120 patients were assigned to either PF or IMF. Cure was defined by a DASH score of 8 or less. Complications were noted as present or not present for each follow up moment and a panel of experts provided weights to the severity of complications. STIs were reported along with their 95% confidence intervals. The higher a procedure's STI, the higher the benefit/risk balance of that procedure.

Results

The non-weighed STI after 6 weeks was significantly higher in the PF group. During further follow up the differences level out and turned non-significant. When weighing the STI for severity, the indices decrease but are significantly in favor of the PF group at 6 weeks and 6 months after surgery. At one year postoperatively, differences are not significant.

Conclusion

The STI may be a reliable tool to assess the benefits and risks of operative fracture treatment. Further studies with consistent results of this new scoring system are needed, before conclusions can be generalized. When determining the indices of PF and IMF, a significant difference in favor of PF was observed during the early phase of recovery.

Level of Evidence: I

Key words: clavicle fractures; displaced; operative treatment; surgical therapeutic index; plate fixation; intramedullary fixation

Introduction

In recent years, the Surgical Therapeutic Index (STI) has been described as an alternative way to present the pros and cons of surgical treatment. The concept was first described in the field of incontinence surgery in the late 1990's.[4] It is similar to and derived from the therapeutic index in pharmacology which describes the ratio of the desired effect of a certain drug to its possible toxic effect.

The STI is defined as the ratio between the cure rate and complication rate of a surgical intervention. The definition of cure, naturally, depends on the patient's primary source of pathology. Determining the complication rate at a specific moment in time is the sum of all complications associated with the performed surgical procedure. Severity factors can be added to grade the degree of complications and its consequences.[8] The index should be interpreted as expressing a certain level of safety; the higher a procedure's STI, the safer the procedure. This way, it may play an additional informative role in pre-operative counselling of a patient and helping him or her in deciding on the optimal surgical treatment. Contrary to well known measures of effectiveness of surgical interventions such as Number Needed to Treat (NNT),[12] the STI also accounts for complications and the consequences there of. In addition, parameters like the NNT are mostly used for reviews of multiple studies and not applied to single studies.

The STI has not been applied to the study of trauma care, and of fracture management in particular. The optimal treatment of clavicle fractures has been a topic of debate for many years. Although many of these fractures may be treated conservatively successfully, there has been an increase in surgical fracture treatment of displaced midshaft clavicle fractures (DMCF) in recent years.[15] The most frequently applied surgical techniques are open reduction and internal plate fixation (PF) or (closed) reduction and intramedullary fixation (IMF). The purpose of this study was to introduce the STI in trauma surgery by comparing the indices for surgical PF and IMF for the treatment of DMCF. Our hypothesis was that the index for PF would be higher during the early recovery phase but the indices would be comparable between both groups one year after surgery.

Materials and Methods

Study Population

The study population consisted of 120 patients who suffered a DMCF and participated in the Plate Or Pin trial.[17] Participants in this multi-center, prospective, controlled trial were randomized to either PF or antegrade IMF using a Titanium Elastic Nail (TEN) after Institutional Review Board approval was obtained. Postoperative follow up took place at 6 weeks, 3 months, 6 months and one year after surgery. In the interest of brevity we refer to the study protocol and previously reported objective and patient-oriented outcome for full description of in- and exclusion criteria, operative procedures and (functional) outcome parameters.[16,17] A total of 58 patients were enrolled for PF and 62 for IMF. At baseline, there were no differences between the two groups (Table I).

Operative Technique;

Plate Fixation

Patients were placed in beach chair position and prepped in standard fashion. A longitudinal incision parallel to the clavicle, length of which depended on the fractured segment, was made and the fracture was identified. Following fracture reduction, a plate (DePuy Synthes BV, Amersfoort, The Netherlands) was positioned on the anterosuperior surface of the clavicle and fixated using (non-)locking screws. Plate types were used according to surgical preference.

Intramedullary Fixation

Patients were positioned in the supine position on a radiolucent table. Just lateral to the sternoclavicular joint a small incision was made and the anterior cortex was opened using a pointed reamer. A titanium elastic nail (TEN, DePuy Synthes BV, Amersfoort, The Netherlands or Stryker BV, Waardenburg, The Netherlands) was inserted from the medial side under fluoroscopic control. Fractures were reduced closed under image intensification with percutaneous clamps or, if closed reduction failed, in an open fashion using an additional small incision over the fracture site**.** After complete introduction in the lateral fragment and compression of the fracture, the nail was cut at the introduction point. A more detailed description of both surgical techniques can be found in the study protocol.[17]

Cure

The primary end parameter in the POP study was the Disabilities of the Arm, Shoulder and Hand score (DASH).[7] Depending on age and patient activity, a normal DASH score ranges from 2 to 8.[3,7] For each follow up moment and per intervention group, the cure rate was therefore defined by dividing the number of patients with a DASH score of 8 or less by the total number of patients included in the operative group.

Complications

Complications were grouped as follows: infection (superficial or deep), neurovascular pathology (transient brachial plexus syndrome, hematoma, and desensitized skin), and implant related problems (soft tissue irritation, breakage, and failure), bone-healing problems (nonunion, malunion) and refracture after implant removal.

Redness and swelling with/without purulent discharge at the wound site was considered a superficial infection while infection requiring debridement or implant removal was defined as a deep infection. Paresthesia of the arm and/or fingers were considered transient after spontaneous recovery within 6 months after surgery and defined as transient brachial plexus lesions.[10] A palpable presence of the implant resulting in soft tissue irritation was considered implant irritation. A nonunion was defined as lack of radiographic healing with clinical evidence of pain and motion at the fracture site at 6 months after surgery. Finally, a symptomatic malunion was defined as a shortened, angulated or displaced position of the clavicle on x-ray with clinical symptoms after 6 months.

Complications were scored as present or not present at 6 weeks, 3 months, 6 months and 1 year postoperatively. In case of two different types of complications registered in one patient at the same time, the complication with the most severe treatment consequences was noted. If relevant, treatment by implant removal was taken into account. In case of occurrence of different types of complications in the same patient but at different follow up moments, both types of complications were registered.

The complication rate was calculated in two ways. First, the sum of all types of complications for each surgical group per follow up moment was determined and divided by the number of patients in the corresponding group. For the second calculation, a severity weight was added. These weights correspond to the impact and consequences of the complications noted in terms of further treatment required.

Complication management

Complication management consisted of a self-limiting/’wait-and-see’ policy, treatment with antibiotics, surgical drainage and debridement, minor implant revision, major implant revision and removal of implants under local or general anesthesia. The minor implant revisions, which were performed under local anesthesia, included partial removal of the protruding end of an implant. Major revision was defined as revision of surgical fixation.

Routine implant removal

The removal of implants under local or general anaesthesia was also included in the complication rate, even when performed routinely according to the treating physicians practice. Routine removal was not described in the original study protocol.[17]

Surgical Therapeutic Index; Severity Factors

There were no previously published studies on the STI and clavicle fractures for reference. Three expert trauma surgeons (L.P.H.L., M.H.J.V and E.J.M.M.V.) were asked to grade the various complications and in particular the subsequent treatment types to manage the complication on a scale of 1-10. A value of 1 represented an uncomplicated postoperative recovery and 10 the worst possible recovery. This additionally resulted in a ranked order in terms of severity for the listed types of complication management. The number of experts was chosen arbitrarily since no guiding literature on the topic was available.

From these data two severity weighing models were determined. Model 1 consisted of the mean values assigned by the experts for each complication management type. Model 2 consisted of the ranked order of severity of complication management. Finally, the STI was defined by dividing the cure and complication rates, respectively. The STI was determined at 6 weeks, 3 months, 6 months and 1 year after surgery. In case of a successfully treated complication at, for instance, 6 months, this complication was not included for STI determination during final follow up after 1 year. This way, if the complication rates decreases, the STI can increase if the cure rate stays the same. This demonstrates a progress of the indices over time.

Statistical Analysis

The unpaired Student's t-test was used to compare continuous variables and the X^2-test for dichotomous variables comparison. Inter-rater reliability reflecting the consistency among the three experts concerning their severity weighing of complications was determined by calculating the two-way mixed intra-class correlation coefficient for average measures.

After bias correction and using nonparametric bootstrapping, surgical therapeutic indices were compared by their confidence intervals.[8,13] The principle of bootstrapping relies on random sampling with replacement. Sample sizes similar to the original sample separately for each group and with replacement were drawn 1000 times. Bootstrapping was used to generate both 83% and 95% confidence intervals. The latter ones were used for reporting, but the significance of observed differences was defined as absence of overlap of the respective 83% confidence intervals.[1] Statistical analysis was performed using version 20.0 of the Statistical Package for the Social Sciences (SPSS) for Windows (SPSS, Chicago, IL, USA). A p-value of <0.05 was set for statistical significance.

Results

One year after surgery 50 patients (86%) in the PF group and 55 patients in the IMF group (89%) were considered cured (*p=0.67,* table II). A summation of complications and consequences for treatment for the entire follow up period is displayed in table III. In the PF group, 3 patients were lost to follow up for reasons unknown. Superficial infection treated with antibiotics occurred in 3 (5%) patients in the PF group and 4 patients (7%) suffered from a complication requiring major surgical revision, one of which was also previously treated for a superficial infection. No nonunions were recorded after IMF. The IM implant did fail in 2 patients (3%) requiring revision fixation for which plate and screw fixation was applied.

Ten patients underwent minor revision in the IMF group but all eventually progressed to total implant removal due to persistent soft tissue irritation. Eleven patients had their implant removed in routine fashion without experiencing prior soft tissue irritation. In the PF group, five patients had the implants removed at their specific request.

The inter-relater reliability based on consistency of the questioned experts was 0.95 (0.82 – 0.99). This correlates with excellent agreement.[9] The assigned mean values (model 1) and mean ranked order (model 2) for complication management are displayed in table IV.

The unweighed STI after 6 weeks was significantly higher in the PF group. During further follow up the differences leveled out and were not significant (Table V). When weighing the STI following models 1 and 2, the indices were significantly in favor of the PF group at 6 weeks and 6 months after surgery. At 3 months and one year postoperatively, differences were not significant.

Discussion

This study introduces a tool to assess the benefits and risks of operative fracture treatment. The STI enables medical personnel as well as patients to easily weigh the benefits and adverse sides of different surgical techniques; the higher a procedure's STI, the higher the benefit/risk balance of that procedure. Initially, it may be hard to place the outcome of the STI into context. We emphasize, therefore, that the message of this study is not to be found in the absolute numbers considering the inability to compare with previous studies, but perhaps more to present an alternative rationale to choose between different surgical techniques. Clinical usefulness of which, has previously been reported in different areas of medicine. [8]
Introduction of a new scoring tool poses certain questions. In this case: what defines cure? And even more so, does every complication have similar impact on patient recovery? Although a slight variation in DASH score in the healthy population is noted, we believe that assuming the lower margins of this 'healthy' function score safely represents a cured patient. The DASH score was chosen to define cure given its' subjective nature. The rating of complications and in particular the impact of different types of complications on overall patient recovery, however, was more difficult. The severity weighing was applied to bear meaning to the differences in absolute numbers of complications and the extent of possible consequences. One can imagine that a self-limiting complication is inconvenient yet it does not have the implications of, for instance, a revision surgery. Also, several patients in the PF group explicitly requested the implant to be removed upon fracture healing which brings the hazards of reoperation under general anaesthesia. This also accounted for many patients in the IMF group despite the proclaimed possibility to perform implant removal under local anaesthesia.

Our hypothesis was that STI’s would be higher for PF during the early postoperative phase but similar between groups one year after surgery which was confirmed. The number of patients cured was comparable among the two groups although there was a trend in favor of the PF group during the early recovery phase. In combination with fewer early postoperative complications, in particular implant related soft tissue irritation, this resulted in a higher STI than the IMF group. The application of severity weights naturally lowers the indices for both groups but also created significant differences in favor of the PF group at two moments of follow up: 6 weeks and 6 months after surgery. This can be explained by the severity weights assigned to implant removal and major surgical revision. At 3 months postoperatively, the rate of implant removals and surgical revisions is equally low. At 6 months, however, the implant removal rate in the IMF group is much higher corresponding with a lower STI. It should be mentioned that at one point in the analysis the STI is in favor of IMF, although not significant. This is without severity weighing at one year after surgery. The advantage of the IMF at this stage can be explained by the occurrence of late major complications such as clavicle refracture after plate and screw removal in the PF group. It should be noted that fracture characteristics, such as simple or complex fractures, did not influence outcome.

Overall, the gradual decrease in STI for PF and relatively stable STI for IMF are remarkable. They can be explained by the high rates of implant related soft tissue irritation. Surgeons tend to leave plate and screw constructs in situ unless removal is absolutely warranted or explicitly requested by the patient. If performed, removal generally takes place after full recovery and always requires general anesthesia. TENs were often removed sooner and removals were distributed more evenly during the entire follow up period. Despite the proclaimed advantage that IM devices can preferably be removed under local anesthesia, this was only performed in 22% of TEN removals, regardless of the presence of implant related irritation. We believe that the high rates of implant related soft tissue irritation, also in comparison to previous studies,[2,5,6,11,14,18] stresses the importance of meticulous operative technique and in case of IMF, routine implant removal upon achieving fracture union.

Several study limitations need to be addressed. First, the number of patients included is relatively low. This introduces the risk of type II errors and the possibility that very rare, but disabling complications have accidentally not been observed in our cohort. For example, brachial plexus lesions after IMF are rare, but have been described.[10] One iatrogenic brachial plexus injury will change the STI immediately. Ideally, a STI is continuously updated with more recent patient data and its reliability therefore improves. Secondly, we opted to base the severity factors on the opinion of three skilled surgeons, considering their experience with the complications at hand. A larger group of experts will reduce the dispersion in the assessment of severity. Moreover, in times in which patient reported outcome measures are increasingly important, it would also be interesting to survey the patient population for their opinion. A third limitation of our current study is that multiple, but contemporary complications in one patient, only the most severe treatment consequence was noted. This could have led to relatively optimistic STI's. However, this only occured in one patient who experienced hypoesthesia around the operation scar and soft tissue irritation due to the implant at the same follow up time point.

With regards to inter-rater correlation of the severity weights, deep infections requiring surgical debridement did not occur in this study but were nevertheless assigned a severity factor for possible future applications in other patient populations. This did, however, not influence the inter-rater reliability based on consistency.

Conclusions

The Surgical Therapeutic Index may be a reliable tool to assess the benefits and risks of operative fracture treatment, but additional study of clavicle and other fractures is needed before the conclusions can be generalized. When determining the indices of PF and IMF, a significant difference in favor of PF was observed during the early phase of recovery, which was also present at 6 months after surgery when correcting for the gravity of consequences of complications by using severity factors. One year postoperatively, the STI for PF and IMF were similar.

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Table legends

Table 1. Baseline characteristics per group. PF = Plate Fixation. IMF = IntraMedullary Fixation.

SD = Standard Deviation. BMI = Body Mass Index (kg/m2)

*Fracture Classification according to Orthopaedic Trauma Association[7]

Preoperative data		PF (n = 58)	IMF (n = 62)	*p-values*
Age (years; mean ±SD)		38 (15)	40 (13)	*0.64*
Gender (n, %)	Male	53 (92%)	60 (97%)	*0.21*
	Female	5 (8%)	2 (3%)	
BMI (kg/m2; mean ± SD)		24.7 (3.5)	24.2 (3.0)	*0.36*
Smokers (n, %)	Yes	19 (33%)	20 (32%)	*0.9*
	No	38 (67%)	42 (68%)	
Fracture side (n, %)	Right	30 (52%)	29 (47%)	*0.59*
	Left	28 (48%)	33 (53%)	
Trauma mechanism (n, %)	Traffic accident	28 (48%)	25 (40%)	*0.17*
	Sports	18 (31%)	29 (47%)	
	Fall or other	12 (21%)	8 (13%)	
Fracture Classification (n, %)*	Simple	27 (47%)	24 (39%)	*0.58*
	Wedge	29 (50%)	34 (55%)	
	Complex/Comminuted	2 (3%)	4 (7%)	

Table 1. Baseline characteristics per group. PF = Plate Fixation. IMF = IntraMedullary Fixation.
SD = Standard Deviation. BMI = Body Mass Index (kg/m2)
*Fracture Classification according to Orthopaedic Trauma Association[7]
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Table 2. Number of patients cured per operative group for each follow up moment.

Cure is defined as the number of patients with a DASH score of 8 or less.

PF = Plate Fixation. IMF = IntraMedullary Fixation.

Follow up	PF (n = 55)	IMF (n = 62)	*p-value*
6 weeks	32 (55%)	25 (40%)	*0.54*
3 months	47 (81%)	44 (71%)	*0.60*
6 months	50 (91%)	50 (81%)	*0.12*
1 year	50 (91%)	55 (89%)	*0.67*

Table 2. Number of patients cured per operative group for each follow up moment.
Cure is defined as the number of patients with a DASH score of 8 or less.
PF = Plate Fixation. IMF = IntraMedullary Fixation.

T**able 3.** Total registered complications and treatment per operative group after final follow up. PF = Plate Fixation. IMF = IntraMedullary Fixation

Complication		Management		Overall	
				PF (n = 55)	**IM**
Infection*	*Superficial*	*Antibiotics*		3	
	Deep	*Surgical drainage*		0	
Hypesthesia, haematoma		*Observation*		5	
Transient neuralpraxia		*Observation*		0	
Soft tissue irritation due to implant		*Observation*		12	
		Minor revision		0	
		Hardware removal	*Local Anaesthesia*	0	
			General Anaesthesia	17	
Implant breakage		*Major revision*		1	
Implant failure		*Major revision*		0	
Non-union		*Major revision*		1	
Mal-union		*Major revision*		0	
Refracture after implant removal		*Major revision*		2	

T**able 3.** Total registered complications and treatment per operative group after final follow up.
PF = Plate Fixation. IMF = IntraMedullary Fixation
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Table 4. Assigned severity weights for each type of complication and subsequent management.

Three expert trauma surgeons (L.P.H.L., M.H.J.V and E.J.M.M.V.) were asked to grade the various complications and in particular the subsequent treatment types to manage the complication on a scale of 1-10. A value of 1 represented an uncomplicated postoperative recovery and 10 the worst possible recovery. This additionally resulted in a ranked order in terms of severity for the listed types of complication management. From these data two severity weighing models were determined.

Weigh Model 1 consists of the mean values assigned by experts.

Weigh Model 2 consists of the mean ranked order of severity of complications.

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Complication management		Model	
		Mean Value (1)	**Mean Rank (2)**
Self-limiting / Wait-and-see		3.3	1.5
Antibiotics		4	2
Surgical drainage		8	6.5
Minor revision		4.7	2.7
Hardware removal	*Local Anaesthesia*	5.3	3.8
	General Anaesthesia	6.3	5
Major revision		8	6.5

Table 4. Assigned severity weights for each type of complication and subsequent management.
Three expert trauma surgeons (L.P.H.L., M.H.J.V and E.J.M.M.V.) were asked to grade the various complications and in particular the subsequent treatment types to manage the complication on a scale of 1-10. A value of 1 represented an uncomplicated postoperative recovery and 10 the worst possible recovery. This additionally resulted in a ranked order in terms of severity for the listed types of complication management. From these data two severity weighing models were determined.
Weigh Model 1 consists of the mean values assigned by experts.
Weigh Model 2 consists of the mean ranked order of severity of complications.

Table 5. Surgical Therapeutic Indices (STI) per operative group at each follow up moment with and without correction for severity factors.

Weigh factor 1 consists of the mean values assigned by experts. Weigh factor 2 consists of the ranked order of severity of complications.

* = significant difference. CI = Confidence Interval.

PF = Plate Fixation. IMF = Intramedullary Fixation

STI - Unweighed (95% CI)	**PF**	**IMF**
*6 weeks (95% CI)**	3.6 (1.6 - 7.8)	1.2 (0.7 - 1.9)
3 months (95% CI)	3.3 (1.9 - 5.8)	3.5 (1.9 - 7.0)
6 months (95% CI)	4.5 (2.4 - 8.6)	3.3 (2.1 - 5.5)
1 year (95% CI)	4,5 (2.3 - 9.3)	10.8 (2.1 - 49.9)
STI - Model 1 weighing (95% CI)		
*6 weeks (95% CI)**	0.9 (0.5 - 1.9)	0.3 (0.2 - 0.4)
3 months (95% CI)	0.8 (0.5 - 1.5)	0.4 (0.3 - 0.8)
*6 months (95% CI)**	0.7 (0.4 - 1.4)	0.3 (0.2 - 0.5)
1 year (95% CI)	0.4 (0.2 - 0.5)	0.3 (0.2 - 0.4)
STI - Model 2 weighing (95% CI)		
*6 weeks (95% CI)**	1.9 (1.0 - 4.2)	0.5 (0.3 - 0.9)
3 months (95% CI)	1.6 (0.8 - 3.3)	0.7 (0.4 - 1.3)
*6 months (95% CI)**	1.2 (0.5 - 2.7)	0.5 (0.3 - 0.8)
1 year (95% CI)	0.5 (0.3 - 0.8)	0.4 (0.3 - 0.5)

Tabel 5. Surgical Therapeutic Indices (STI) per operative group at each follow up moment with and without correction for severity factors.
Weigh factor 1 consists of the mean values assigned by experts. Weigh factor 2 consists of the ranked order of severity of complications.
* = significant difference. CI = Confidence Interval.
PF = Plate Fixation. IMF = Intramedullary Fixation