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ORIGINAL ARTICLE

Coagulation Profile is Randomly done but Never Helps in Preparation of Laparoscopic Surgery

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ABSTRACT

Study objective: To assess the usefulness of practicing preoperative coagulations tests in preparation of laparoscopic surgical procedures.

Design: Retrospective observational study.

Setting: King Fahad Medical City a tertiary-care referral center in Saudi Arabia.

Method: Five hundred and fifty adult patients scheduled for elective laparoscopic surgery were studied to determine whether plan of management was influenced by routinely done bleeding time (BT), platelet count (PC), prothrombin time (PT), activated partial thromboplastin time (APTT) and international normalization ratio (INR).

Results: No intervention or change of management was identified in 463 patients whom coagulation profiles were done routinely as part of preoperative preparation. However, management plan was changed in 5 (5.75%) of 87 patients having indications for coagulation profile test ($p < 0.01$).

Conclusion: The study shows that preoperative screening tests for coagulopathies not suspected on the basis of detailed clinical information are unnecessary and should not be done.

Keywords: Coagulation profile, Indicated test, Indication, Intervention, Screening test.

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INTRODUCTION

Prothrombin time (PT) and activated partial thromboplastin time (APTT), international normalization ratio (INR), platelet count (PC) and bleeding time (BT) are commonly ordered by clinicians as part of preoperative assessment. In preparation of patient for laparoscopic procedure these tests are never missed in KSA and some other countries like India. In Bangladesh though coagulation profile is not mandatory for all patients but still it is widely practiced by the surgeons and anesthesiologists before laparoscopic procedure.

Evidence-based guidelines on the use of preoperative tests before elective surgery have been published by the national institute for clinical excellence (NICE) a government organization in the UK in 2003 where these tests were not recommended routinely either in adult or in children before elective procedure in the absence of positive family or personal history of bleeding disorder. More recently British Committee for Standards in Haematology has confirmed the NICE guidelines appropriateness regarding this.[2] American Society of Anesthesiology (ASA) has published an advisory in 2002 saying that patient with negative abnormal bleeding history does not require coagulation screening prior to surgery.[3] A prospective study showed proper history taking can safely and effectively supplement preoperative screening test for coagulopathy.[4] British committee for standards in haematology also stated that unnecessary testing can delay surgery in appropriately because of low positive predictive value of these tests.[2] Canadian anesthesiologist society (CAS) published a simple guidelines regarding routine preoperative coagulation test.[5] In a systemic review done in Johns Hopkins University School of Medicine in 2005 conclude that there is very insufficient evidence to conclude that abnormal test results predict peroperative bleeding and suggested RCT to provide strong evidence.[6] On the other hand, Italian Society for Haemostasis and thrombosis recommended that PT, PTT, INR should be performed routinely before any invasive or surgical procedure.[7] There are many other studies and case reports supporting preoperative some sorts of coagulation profile.[8,9] Most of the country in Europe follow NICE guidelines and some other country is trying to prove this thought in their population for specific

operations. For instance, coagulation status is routinely checked before any operative procedure in Germany but German Society for Ear-Nose-Throat-Medicine, Head and Neck Surgery (DGHNO), the Working Group Paediatric Anaesthesiology of the German Society of Anaesthesiology and Intensive Care Medicine (DGAI), the German Society of Paediatric Medicine (DGKJ), and the Paediatric Committee of the German Society of Thrombosis and Haemostasis Research (GTH), published in the Deutsches Ärzte blatt in 2006, stressed that coagulation screening is not useful in the preoperative setting and advised to draw more attention on the patient's detailed history.[10]

It is obvious that preoperative routine coagulation profile is still in practice and a matter of contention between the physicians. In most of the country, it is considered as an obligatory part of preoperative evaluation for laparoscopic surgery. One of the reasons behind that is surgeon is very much cautious about bleeding during laparoscopic procedures, others are more general, to detect unsuspected abnormalities that might influence the risk of operative morbidity and mortality; establishing a baseline value for a test that has a likelihood of being monitored and changing after the surgical procedure; for medicolegal reasons; and as a tradition in individual institutional practices.

Here in Saudi Arabia, we found that no patients undergo elective surgical procedures without coagulation testing. In our institution, a tertiary referral hospital in the capital drawing a general catchment from all over the country PT, PTT, INR, BT and PC is a routine practice for all elective surgical patients. Science already proven that routine preoperative investigations is not necessary by the major medical societies of the world, we decided to check if there is any role of coagulation profile in preparation of patient for laparoscopy surgery.

STUDY DESIGN

Retrospective chart review.

SETTINGS

Department of surgical specialties, King Fahad Medical City a tertiary care super specialized referral center, Riyadh, Saudi Arabia.

METHODS

Upon approval from institutional review board (IRB) all patients underwent elective laparoscopy surgery in the year 2009 was identified from operation theater and anesthesia department co-ordinated data base system. We excluded pediatric patients, emergency procedures and pregnant patients. Elective surgery was defined as scheduled operation list published and distributed day before surgery.

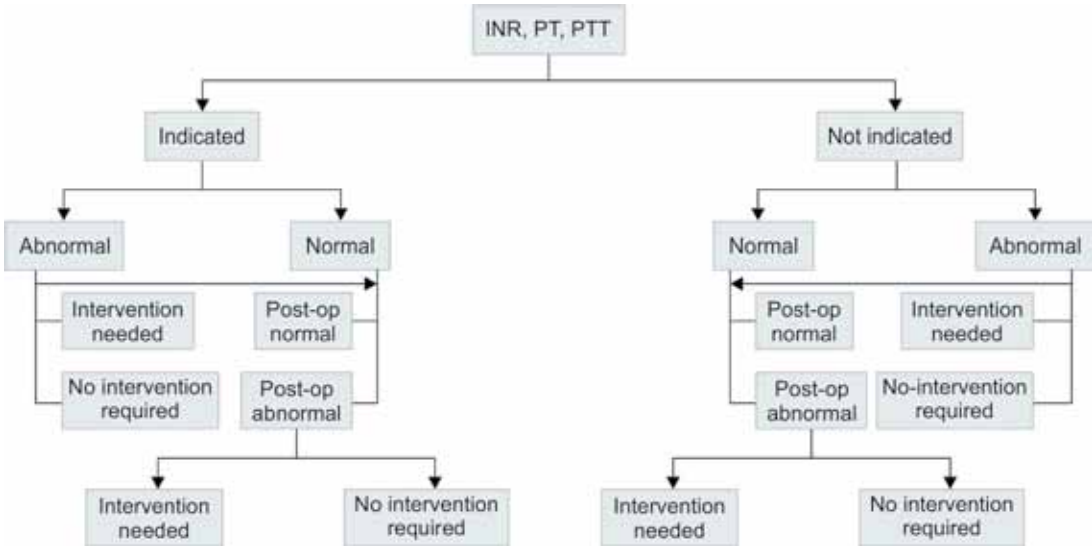
To identify patients predisposed to an abnormal coagulation system, a comprehensive list of indications (Table 1) for preoperative coagulation testing was derived with guidance of CAS guidelines, ASA advisory and Harvard medical school study.[11] Based upon the listed questionnaire patients file was reviewed to divide them into 'Indicated test group' and 'Screening test group'. Indicated test group patients were those whom coagulation test results might had been abnormal due to specific findings in history and physical examination. Screening tests group patients were those whom these investigations were not specifically needed; therefore, were done as screening for an unsuspected coagulopathy (Flow Chart 1).

Preoperative INR, PT, PTT, BT and PC results recorded from hospital electronic data base system. Postoperative results (up to 28 days postoperative period) also searched and recorded when available. Any change of management plan to overcome the abnormal results termed as 'Intervention', was identified from physician order documented in the file. Cancellation of procedure, transfusion of packed RBC, whole blood in excess of normal due to coagulopathy, transfusion of fresh frozen plasma, platelets, or other coagulation factors and Vit K

Table 1: Indications to request preoperative coagulation profile

• Bleeding diathesis, Family history of bleeding disorder	Prolonged bleeding
	Excessive bleeding
	Easy bruising
	Unable to give history
• Anticoagulant therapy	Aspirin
	Heparin, Enoxaparine
	Dipyridamole
	Warfarin
	Nonsteroidal anti-inflammatory drugs
• Past medical history	History of deep venous thrombosis or pulmonary embolism.
	Chronic renal failure on dialysis
	Cirrhosis, jaundice
	Splenic disease
	Platelet dysfunction
	Thrombocytopenia
• Malignancy	Metastatic carcinoma
	Malignancy with radio-chemotherapy
• Physical examinations	Petechiae
	Ecchymosis
	Jaundice
	Hepatomegaly, nodular liver
	Ascitis
	Splenomegaly

Flow Chart 1: Study scheme showing group differentiation



injection were taken as intervention, whereas preparation of packed RBC or total blood in an operative procedure where generally not ordered is also considered as change of management. Preoperative blood transfusion for anemia or blood transfusion for major surgery in absence of positive bleeding history was not considered as interventions for coagulation profile tests.

Statistical comparisons between the two groups in context of required interventions were made using Fisher's exact test, with the level of significance taken as $p < 0.05$.

RESULTS

A total 550 adult patient underwent elective laparoscopic surgery, of them 461 (83.82%) patients was female (Table 2). Laparoscopic cholecystectomy (Table 3) was the commonest procedure 245 (44.55%).

Among the 87 patients whom the coagulation profile was indicated, 14 (16.09%) patients had abnormal results, requiring intervention preoperatively for 5 (5.75%) patients (Table 4). Four hundred and sixty-three patients were in the screening test group. Of those, 455 (98.27%) patients were found to have normal results. Even the 8 (1.73%) patients with abnormal results did not require any intervention. The difference in the change of management (Table 4) between the two groups were highly significant ($p < 0.01$).

Among the test indicated group test was repeated at least once or multiple times in 45 patients (Table 5). Nine patients had once or more than once abnormal results and interventions were needed in 4 patients. On the other hand, 113 patients of the screening group were found to have coagulation profile repeated within 28 days postoperative period, only three patients had abnormal results, again not needing any active management.

DISCUSSION

The current study is the first ever evaluation regarding the usefulness of routine preoperative coagulation testing in case of only laparoscopic surgery patients. Comprehensive criteria derived from the patient history and physical examinations were used to determine that preoperative coagulation testing was indicated or not. The questionnaire was designed to supplement the standard history and physical examination by the chart reviewing physicians. It was made by assistance of a number of strong

Table 2: Demographic data and distribution of patients

Patients (n)	*Number*	*Percentage*
Total	550	100
Male	89	16.18
Female	461	83.82
General surgery	301	54.72
Gynecology	224	40.73
Urology	25	04.55

Table 3: Laparoscopic procedures performed

Name	*Number*	*Percentage*
Laparoscopic cholecystectomy	245	44.55
Laparoscopic ovarian cystectomy/ Oophorectomy/salpingo-oophorectomy	63	11.46
Total laparoscopic hysterectomy and laparoscopy-assisted vaginal hysterectomy	62	11.27
Diagnostic laparoscopy with or without hysteroscopy	46	8.36
Laparoscopic myomectomy	29	5.27
Laparoscopic sleeve gastrectomy	23	4.18
Laparoscopic colorectal procedures	20	3.64
Laparoscopic pancreatectomy, splenectomy, adrenalectomy, Nephrectomy	17	3.09
Laparoscopic vericocelectomy	13	2.36
Others	32	5.82
Total	550	100

Table 4: Summary of the coagulation profile results ($p < 0.01$)

Test indicated			*Screening test*		
Normal	*Total abnormal*	*Abnormal with intervention*	*Normal*	*Total abnormal*	*Abnormal with intervention*
73	14	5	455	8	0
83.91%	16.09%	5.75% (35.71%)*	98.27%	1.73%	—
Total number of patients = 87 (15.82%)			Total number of patients = 463 (84.18%)		

*35.71% of abnormal results (5 of 14) needed intervention which were 5.75% of total (5 of 87)

Table 5: Available postoperative coagulation profile results ($p < 0.01$)

Test indicated group			*Screening test group*		
Normal	*Total abnormal*	*Abnormal with intervention*	*Normal*	*Total abnormal*	*Abnormal with intervention*
36	9	4	110	3	0
Total number of patients = 45			Total number of patients = 113		

international guidelines CAS, ASA and Harvard medical school study to keep the evaluation process simple and which can be a tool for the surgeon and anesthetist for preoperative assessment of patient in future. When these criteria were applied to the general, gynecological and urological elective surgery patients who had been operated laparoscopically, 87 (15.82%) of them had at least one indication for the test. In 84.18% (463) of the patient test were not indicated were truly screening tests for an occult coagulopathy because they could not have been otherwise suspected. Although 1.73% of the screening tests were abnormal, all ignored by the surgeon and anesthetist, because they were marginally prolonged. Literature also suggests that minimally deranged coagulation result have a poor predictive value for a surgically significant coagulopathy.[12] Following an abnormal test result clinicians may go for correction of it, whereas a serious abnormality may suggest the surgery to be cancelled or delayed. But commonly most abnormalities are simply ignored. As per Roizen MF clinicians ignore more than 60% of abnormalities discovered on routine preoperative tests.[13] In our patients, 35.71% of abnormal results in indicated test group were taken for active management by the physicians others were simply ignored, whereas all[8] the abnormal results were amenable to overlook in screening test group.

Postoperatively (up to 28 days), some patients with major surgery and had to stay in hospital for couple of days, found to have repeat coagulation profile. Again there was no intervention identified in screening test group in comparison to four interventions in patients of indicated test group. We did not put emphasis on these findings in our study as all the patient had not gone through the same investigations after operation, although it gave an idea that illogical coagulation profile has no role in laparoscopic surgical procedures even in postoperative period.

Our study is retrospective; our control and study groups were not matched in number, age and sex, which could have influenced our test of significance. Most of our patients are female 461 (83.82%) this was because gynecological laparoscopic procedures 224 (40.73%) were included in the study. Moreover, our single most performed surgery was laparoscopic cholecystectomy which was also overtly dominated by female. We found a relatively high number of abnormal results in the screening test groups because we followed our local hospital definitions of abnormal results, rather than the more practical 'action limits'. We also considered total test result as abnormal when any component of the test breached the reference value. For instance, we labeled total coagulation profile as abnormal when any one of PT, APTT, INR, BT or PC being abnormal, As such, very few actual interventions were needed for these abnormal results. We considered the change of management plan named as intervention to differentiate between the results of two groups, as minor change of test value has no real benefits to calculate. Test values also fluctuate by reagent used and analyzer machines.

In summary, we could not appreciate any special clue or danger to carry on with the same traditional practice of routine preoperative coagulation tests for laparoscopic procedures. The results of our study show that most tests 84.18% (463, Table 4) ordered at our institution are incompatible with the applicable published guidelines. To follow established guidelines is usually the exception and not the rule in the majority of health institutions in the World. This failure to convert recommendations into practice is often not related to the content or quality of the guidelines themselves but is more related to difficulty changing established behavior of clinicians and institutions in addition to failure of dissemination, cost, and doubt of guideline's applicability in local populations.[14] We hope that our study result will be a guideline for asking coagulation profile tests in KSA as well as Bangladesh which will reduce the unnecessary financial burden on the society and patients.

CONCLUSION

It can be suggested based on our findings that routine preoperative PT, APTT, INR, BT, PC can be safely eliminated from preparation of patient for laparoscopic procedures by careful history taking and clinical examinations without endangering patient's life or adversely affecting the outcome.

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