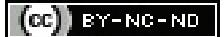


Evaluating Compliance of Preoperative Investigations with National Institute for Clinical Excellence Testing Guidelines for Patients undergoing Elective Surgery: An Observational Study

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ABSTRACT

Introduction: All patients posted for surgery are subjected to a series of tests. Recent studies have shown that many of these tests may not be necessary as they do not alter the anaesthetic technique. There are many international guidelines for ordering preoperative investigations.

Aim: To determine the proportion of patients who underwent compliant testing and to identify the most common investigations which were not compliant with National Institute for Health and Care Excellence (NICE) guidelines.

Materials and Methods: This was a prospective observational study conducted on all patients undergoing elective surgery at Sri Devaraj Urs Medical College and RL Jalappa hospital, Kolar,

Karnataka, India, from May 2022 to July 2022. The grade of surgery and the American Society of Anaesthesiologists (ASA) Physical Status of the patients were noted. The compliance of the tests with NICE guidelines was noted.

Results: The preoperative investigations were done in 60 adult patients undergoing elective surgery. Renal function tests were the most non compliant (60%) as per NICE guidelines. Echocardiography (ECHO), Thyroid function tests and Electrocardiography (ECG) were compliant in 78.3%, 91.7% and 60% of the patients, respectively.

Conclusion: The tests which were most non compliant were coagulation profile and renal function tests. Further studies need to be conducted to check compliance with Indian guidelines.

Keywords: Compliance, Elective surgery, Guidelines, Necessary investigations

INTRODUCTION

All patients posted for surgery are subjected to preoperative evaluation. This evaluation is to determine the fitness of a patient based on clinical examination and history. Many tests are advised, most of which are mainly screening tests. Recent studies have questioned the usefulness of routine blood investigations. The preoperative investigations help to confirm diagnosis, assess severity of the disease, progression of the disease and predict the prognosis. On the other hand, performing preoperative investigations in asymptomatic patients or healthy patients causes unnecessary expenditure to the patients and these tests have hardly been a reason for a change in anaesthetic and surgical technique [1-3].

The NICE [4] and ASA have developed practice advisories that are intended to assist decision making in areas of patient care. NICE guidelines first came into practice in 2008 (NICE Guidelines CG3) and updated in 2016. The guidelines for preoperative investigations consider only patients scheduled for elective surgery. The patients should be aged above 16 years. These guidelines not only help the doctors but also the patients and their families by reducing the unnecessary costs and stress. In the United Kingdom, the use of these guidelines regularly has reduced the number of tests ordered in the preoperative period [5].

Czoski Murray C et al., conducted a systematic review and concluded that the strategy has led to substantial resource savings [6]. Various professional bodies from all across the world have published guidelines for preoperative testing. In spite of these guidelines, the clinical practice is not uniform. The numbers of tests ordered in the preoperative period are not uniform across the world. Socio-economic, demographic and medico-legal differences

across the world are some of the reasons for this disparity. In the Indian subcontinent, the common prevalence is ordering from minimal needed to battery of investigations. Once the auto analysers were introduced in India, it became a practice to routinely order a set of investigations [7]. Keshavan VH and Swamy CM showed that a good pre-operative assessment of the patient by the anaesthesiologist would reduce the number of unnecessary investigations without any lapse in patient care [8]. Healthcare costs are increasing in the country and one of the areas where one can make a difference is by reducing investigations and limit ourselves to only those that are necessary as per the guidelines.

This study was conducted with the primary objective being determining the proportion of patients who underwent compliant testing. The secondary objectives were to identify the most common investigations which were not compliant with NICE guidelines.

MATERIALS AND METHODS

This was a prospective observational study undertaken from May 2022 to July 2022. The Institutional Ethical Committee (IEC) approval (SDUMC/KLR/IEC/577/2021-22) and CTRI approval (CTRI/2022/04/041871) were obtained. Neither the surgeons nor the anaesthesiologists were aware of the study.

Inclusion criteria: Patients between 18-70 years of age, of either gender, belonging to ASA Physical Status I,II,III and IV posted for elective surgeries, giving informed consent were included in the study.

Exclusion criteria: Patients posted for repeat surgeries and pregnant women were excluded from the study.

Sample size estimation

Formula: Sample size= $4pq/d^2$

$p=75\%$ [1]
 $q=(100-75)=25$
 d -Relative precision of 15% of 75=11.25
 $n=4 \times 75 \times 25 / (11.25)^2$
 $n=7500/126.5=59.2$
 $n=60$

The sample size was calculated to be 60.

All the patients were evaluated on the day before surgery. All the laboratory investigations ordered the number of times they were ordered were noted. The following 10 investigations were examined- haemoglobin, coagulation profile, random blood glucose, serum electrolytes, liver function tests, renal function tests, Electrocardiogram, Chest X-ray, Thyroid function tests and Echocardiogram. In the study institution, the basic preoperative investigations are ordered by the operating surgeon. The operating surgeons were not aware of the study. One researcher was involved in the collection of data. Based on the NICE Guidelines, surgery was graded as minor, intermediate and major. The ASA physical status of the patients was also defined. The preoperative examination was done- the history of the patient was noted and physical examination of the patient done. This was done to see if the investigations were necessary or not.

After considering the age of the patient, grade of the surgery and ASA physical status, investigations which were necessary as per NICE guidelines were categorised as compliant and those that are not required were categorised as non compliant.

STATISTICAL ANALYSIS

Descriptive and inferential statistical analysis has been carried out in the present study. Results on continuous measurements are presented on Mean±SD (Min-Max) and results on categorical measurements are presented in Number (%). Significance was assessed at 5% level of significance. Chi-square/Fisher-exact test has been used to find the significance of study parameters on categorical scale between two or more groups, non parametric setting for qualitative data analysis. Fisher-exact test used when cell samples are very small (0.05). The Statistical Package for the Social Sciences (SPSS) 22.0, and R environment ver.3.2.2 were used for the analysis of the data and Microsoft word and Excel have been used to generate graphs and tables.

RESULTS

A total of 60 patients, posted for elective surgery during the study period, were selected for the study [Table/Fig-1].

| Variables | Frequency |
|---------------------|--------------------------------|
| Age (years) M±SD | 45.1667±3.871 |
| Gender, n (%) | Male 33 (55%), Female 27 (45%) |
| ASA, n (%) | I-41 (68.3%) |
| | II-17 (28.3%) |
| | III-2 (3.3%) |
| Department, n | ENT-19 |
| | Surgery-17 |
| | Orthopaedic-13 |
| | Oncosurgery-7 |
| | Obstetric and Gynaecology-4 |
| Grade of surgery, n | Major-18 |
| | Intermediate-36 |
| | Minor-6 |

[Table/Fig-1]: Demographic data.

The 10 investigations studied and the compliance with NICE guidelines is shown in [Table/Fig-2]. Haemoglobin was the investigation which was 100% compliant with the guidelines. Renal function tests were

the tests which were the most non compliant (60%) as per NICE guidelines. ECHO, Thyroid function tests and ECG were compliant in 78.3%, 91.7% and 60% of the patients, respectively.

| Variables | Gender | | Total | p-value |
|------------------------------|------------|------------|------------|---------|
| | Female | Male | | |
| HB | | | | |
| C | 33 (100%) | 27 (100%) | 60 (100%) | 1.000 |
| NC | 0 | 0 | 0 | |
| Coagulation profile | | | | |
| C | 15 (45.5%) | 12 (44.4%) | 27 (45%) | 0.862 |
| NC | 18 (54.5%) | 15 (55.6%) | 33 (55%) | |
| Random blood sugar | | | | |
| C | 18 (54.5%) | 15 (55.6%) | 33 (55%) | 0.862 |
| NC | 15 (45.5%) | 12 (44.4%) | 27 (45%) | |
| Serum electrolytes | | | | |
| C | 20 (60.6%) | 16 (59.3%) | 36 (60%) | 0.862 |
| NC | 13 (39.4%) | 11 (40.7%) | 24 (40%) | |
| Liver function test | | | | |
| C | 22 (66.7%) | 13 (48.1%) | 35 (58.3%) | 0.236 |
| NC | 11 (33.3%) | 14 (51.9%) | 25 (41.7%) | |
| Renal function test | | | | |
| C | 15 (45.5%) | 9 (33.3%) | 24 (40%) | 0.493 |
| NC | 18 (54.5%) | 18 (66.7%) | 36 (60%) | |
| Electrocardiogram | | | | |
| C | 20 (60.6%) | 16 (59.3%) | 36 (60%) | 0.862 |
| NC | 13 (39.4%) | 11 (40.7%) | 24 (40%) | |
| Chest X-ray | | | | |
| C | 18 (54.5%) | 15 (55.6%) | 33 (55%) | 0.862 |
| NC | 15 (45.5%) | 12 (44.4%) | 27 (45%) | |
| ECHO | | | | |
| C | 24 (72.7%) | 23 (85.2%) | 47 (78.3%) | 0.396 |
| NC | 9 (27.3%) | 4 (14.8%) | 13 (21.7%) | |
| Thyroid function test | | | | |
| C | 29 (87.9%) | 26 (96.3%) | 55 (91.7%) | 0.366 |
| NC | 4 (12.1%) | 1 (3.7%) | 5 (8.3%) | |
| Total | 33 (100%) | 27 (100%) | 60 (100%) | |

[Table/Fig-2]: Investigations frequency distribution.
 C: Compliant; NC: Noncompliant

The investigations like coagulation profile, renal function tests and ECHO were ordered differently by different surgical departments [Table/Fig-3]. Coagulation profile was non compliant in 68.4% of Ear, Nose and Throat (ENT) patients, 76.9% in orthopaedic patients and 52.9% of general surgery patients. The p-value was 0.007 (significant). Renal function tests were non compliant in 84.6% of orthopaedic patients and 73.7% in ENT patients with a significant p-value of 0.006. Coagulation profile, renal function tests, ECG, thyroid function tests and random blood sugar was compliant according to guidelines in 100% of Obstetric and Gynaecology (OBG) patients. Among the general surgery patients, the investigations which were most compliant are ECHO and Liver Function tests. Thyroid function tests and ECHO were the investigations most compliant with guidelines among orthopaedic patients.

DISCUSSION

The inappropriate use of advanced medical technology and services is a major driver of healthcare costs. One such area appears to be routine preoperative investigational services. The purpose of preanaesthesia Evaluation is to collect data about the patient and develop an anaesthetic plan for smooth anaesthesia with no or

| Variables | Department | | | | | Total | p-value |
|------------------------------|------------|------------|------------|--------------|----------|------------|---------|
| | ENT | Surgery | Ortho | Onco Surgery | OBG | | |
| HB | | | | | | | |
| C | 19 (100%) | 17 (100%) | 13 (100%) | 7 (100%) | 4 (100%) | 60 (100%) | 1.000 |
| NC | 0 | 0 | 0 | 0 | 0 | 0 | |
| Coagulation profile | | | | | | | |
| C | 6 (31.6%) | 8 (47.1%) | 3 (23.1%) | 6 (85.7%) | 4 (100%) | 27 (45%) | 0.007 |
| NC | 13 (68.4%) | 9 (52.9%) | 10 (76.9%) | 1 (14.3%) | 0 | 33 (55%) | |
| Random blood sugar | | | | | | | |
| C | 8 (42.1%) | 9 (52.9%) | 6 (46.2%) | 6 (85.7%) | 4 (100%) | 33 (55%) | 0.115 |
| NC | 11 (57.9%) | 8 (47.1%) | 7 (53.8%) | 1 (14.3%) | 0 | 27 (45%) | |
| Serum electrolytes | | | | | | | |
| C | 10 (52.6%) | 9 (52.9%) | 6 (46.2%) | 7 (100%) | 4 (100%) | 36 (60%) | 0.050 |
| NC | 9 (47.4%) | 8 (47.1%) | 7 (53.8%) | 0 | 0 | 24 (40%) | |
| Liver function test | | | | | | | |
| C | 10 (52.6%) | 13 (76.5%) | 4 (30.8%) | 5 (71.4%) | 3 (75%) | 35 (58.3%) | 0.065 |
| NC | 9 (47.4%) | 4 (23.5%) | 9 (69.2%) | 2 (28.6%) | 1 (25%) | 25 (41.7%) | |
| Renal function test | | | | | | | |
| C | 5 (26.3%) | 8 (47.1%) | 2 (15.4%) | 5 (71.4%) | 4 (100%) | 24 (40%) | 0.006 |
| NC | 14 (73.7%) | 9 (52.9%) | 11 (84.6%) | 2 (28.6%) | 0 | 36 (60%) | |
| Electrocardiogram | | | | | | | |
| C | 7 (36.8%) | 11 (64.7%) | 8 (61.5%) | 6 (85.7%) | 4 (100%) | 36 (60%) | 0.068 |
| NC | 12 (63.2%) | 6 (35.3%) | 5 (38.5%) | 1 (14.3%) | 0 | 24 (40%) | |
| Chest X-ray | | | | | | | |
| C | 10 (52.6%) | 9 (52.9%) | 7 (53.8%) | 3 (42.9%) | 4 (100%) | 33 (55%) | 0.490 |
| NC | 9 (47.4%) | 8 (47.1%) | 6 (46.2%) | 4 (57.1%) | 0 | 27 (45%) | |
| ECHO | | | | | | | |
| C | 17 (89.5%) | 14 (82.4%) | 11 (84.6%) | 4 (57.1%) | 1 (25%) | 47 (78.3%) | 0.045 |
| NC | 2 (10.5%) | 3 (17.6%) | 2 (15.4%) | 3 (42.9%) | 3 (75%) | 13 (21.7%) | |
| Thyroid function test | | | | | | | |
| C | 18 (94.7%) | 15 (88.2%) | 12 (92.3%) | 6 (85.7%) | 4 (100%) | 55 (91.7%) | 0.896 |
| NC | 1 (5.3%) | 2 (11.8%) | 1 (7.7%) | 1 (14.3%) | 0 | 5 (8.3%) | |
| Total | 19 (100%) | 17 (100%) | 13 (100%) | 7 (100%) | 4 (100%) | 60 (100%) | |

[Table/Fig-3]: Investigations according to department.

C: Compliant; NC: Non compliant

minimal perioperative morbidity and mortality. Routine preoperative investigations may identify previously unknown conditions that require treatment before surgery or a change in anaesthetic management; however, a false positive finding may result in unnecessary, costly, and potentially harmful treatments or further investigations, causing surgery to be delayed.

Preoperative investigations essentially should be sent after considering the history, clinical assessments, preoperative risk assessment and clinical judgment. There is a difference in the order of preoperative routine tests between surgeons and anaesthesiologists. Anaesthesiologists were more rational in determining the necessity of most routine tests; which in turn proves that the anaesthesiologist-requested tests are more patient-need specific compared to their surgical counterparts [9]. The general practice in the study hospital is ordering of investigations by the surgeon before sending the patient to preoperative evaluation.

In developed countries, there are guidelines like the NICE guidelines for preoperative investigations which are followed. The NICE guidelines categorises surgery as minor, intermediate and major. The co-morbidities of the patients-involving cardiovascular, renal and respiratory systems are also considered. After dividing the patients and the surgeries according to the grade, the set of investigations required can be derived. The NICE guidelines do not include paediatric patients, pregnant patients and patients posted for a redo surgery. Patients

posted for cardiothoracic surgery and neurosurgery are also not included in the guidelines. These were the exclusions in present study.

Though these guidelines have been in place since 2003, modified in 2016, they are not followed in all countries and all hospitals. Many studies have shown that more 50% of the investigations done in the preoperative period are not compliant with the guidelines and have no clinical [9-11]. In a retrospective audit conducted by Kaplan EB et al., at a district hospital in San Francisco showed that coagulation screen was the most frequently requested test performed in excess of those mentioned in the guidelines. Coagulation screening was done in excess in 17.8% of the patients [12]. Haemoglobin was the investigation which was 100% compliant with the guidelines in present study. Renal function tests were the tests which were the most non compliant (60%) as per NICE guidelines. An audit to investigate compliance with NICE guidelines in patients undergoing oral and maxillofacial procedures showed that during the first audit cycle, compliance with guidelines was in 70.6% of the patients and 27.8% of the investigations were performed unnecessarily [13,14].

In the study done by Keshavan VH and Swamy CM, a total of 984 tests were done in 163 patients of whom 52% were not indicated [8]. Abnormal tests were a meager 1.3%. The most common unindicated tests done were echocardiography and chest X-ray (92.5% and 93% respectively). ECHO and ECG were compliant in 78.3% and 60% of the patients, respectively in present study.

In a study by Siriussawakul A et al., Blood Urea Nitrogen (BUN) and creatinine testings were the most frequently overprescribed tests [15]. More investigations tended to be performed on major surgery and younger patients. In the index study, renal function tests were non compliant in 60% of the patients. The department of orthopaedics ordered renal function tests in excess in 84.6% of the patients.

Ranasinghe P et al., (Sri Lanka) found that the investigations with good adherence were urine analysis and ABG (70%-100% compliance) [16]. ECG, FBC, RFT and blood grouping demonstrated moderate adherence (40-69% compliance). Investigations like coagulation profile, ECHO and LFT demonstrated poor adherence (<40% compliance). In present study, haemoglobin was the only investigation which was 100% compliant.

In the study by Remiao MY et al., among the investigations studied, complete blood count and renal function investigations were not compliant with the guidelines in 9% and 14% of the cases [17]. In the same study, chest radiographs, urine analysis, blood gases and lung function requests were compliant with the guidelines in 100% of the patients. In the present study, suggestions for chest X-ray were compliant in only 55% of patients. Hinds S and Hariharan S in the study noted that 64% of the preoperative investigations performed were deemed unnecessary in a Caribbean tertiary care teaching hospital [18]. Relatively healthier patients of ASA I and II physical status had a significantly higher number of unnecessary investigations performed. In a review of preoperative investigations compliance with guidelines by Kumar A and Srivastava U 30-60% tests continued to be greatly in excess of that recommended [19]. Though the guidelines from various professional bodies and many studies done showing non compliance with guidelines, regular practice includes prescribing a series of investigations before elective surgery. The primary reasons given by the perioperative team for performing routine investigations is to avoid being sued for failing to detect subclinical medical problems that may manifest during the perioperative period [2].

This study was done to see the compliance with NICE guidelines in the study hospital with the intention to reduce the economic burden on patients. National guidelines were not in place during the conduct of this study. Future studies to see the compliance with National guidelines may reflect the economic burden better and reduce healthcare costs.

Limitation(s)

This was a single institutional study. The study did not calculate the cost burden of the non compliant tests which would give an exact picture of the healthcare costs.

CONCLUSION(S)

Based on the NICE guidelines, some of the investigations done in preoperative period were found to be non compliant. Haemoglobin was the investigation which was 100% compliant with the guidelines. Renal function tests were the most non compliant (60%). ECHO, Thyroid function tests and ECG were compliant in 78.3%, 91.7% and 60% of the patients, respectively. There was a significant difference in ordering

investigations when analysed based on the department. Among the general surgery patients, the investigations which were most compliant are ECHO and liver function tests whereas Thyroid function tests and ECHO were the investigations most compliant with guidelines among orthopaedic patients. Future studies should check for the compliance with Indian guidelines as they have taken into consideration the socio-economic and medico-legal aspects of the country.

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AUTHOR DECLARATION:

- Financial or Other Competing Interests: None
- Was Ethics Committee Approval obtained for this study? Yes
- Was informed consent obtained from the subjects involved in the study? Yes
- For any images presented appropriate consent has been obtained from the subjects. NA

PLAGIARISM CHECKING METHODS: [Jain H et al.]

- Plagiarism X-checker: Nov 25, 2022
- Manual Googling: Dec 14, 2022
- iThenticate Software: Jan 20, 2023 (24%)

ETYMOLOGY: Author Origin

Date of Submission: **Nov 21, 2022**
Date of Peer Review: **Dec 28, 2022**
Date of Acceptance: **Jan 30, 2023**
Date of Publishing: **May 01, 2023**