Multicentric Study on the Predictive Value of Procalcitonin, C-Reactive-Protein and Lactate for Post-Operative Complication in Colonic Surgery.

Study Steering Committee

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ABSTRACT

Background: Post-operative complications in colonic surgery are quite common reaching an overall estimate of 25%. Some of these complications are associated with reintervention and related to permanent disability.
This multicentric prospective study will try to validate the use of Procalcitonin (PCT), C-Reactive-Protein (CRP) and Lactate as early predictor of complications..

Aim: To explore the correlation of post-operative PCT, CRP and Lactate at 24h, 48h and 72h with complications.

Endpoints: Data collection will focus on patient demographics, operative details, PCT/CRP/Lactate, complications and outcome markers. Several outcomes measures will be used including mortality, morbidity and length of stay.

Primary research question: Do PCT, CRP and Lactate values, alone or in combination offer a valuable method of prediction of post-operative complications?

Methods: This prospective study will be performed in all the Centers invited and interested on participating, and able to provide routine determination of PCT, CRP and lactate. The study will be coordinated by Dr Alessandro Garcea and Dr Luca Ponchietti, working at the Unit of Colorectal Surgery of the University Hospital of Torrevieja, SPAIN.
Sites will be asked to pre-register for the Study and obtain appropriate regional or national approvals.
During the study period all eligible operations will be recorded contemporaneously and followed-up through to 30 days.
The data will be recorded using a standardized pre-determined protocol and a database. The database will be sent to all the participants who will update the ongoing study with the Study Coordinators monthly.
The data will be analyzed and provisional results will be sent to all participants prior to preparing the draft for publication.

Discussion: The data obtained could be of future assistance in delivering optimum of care to patient undergoing colonic surgery.

1 - Introduction

There is a growing interest in finding biological markers useful for early detection of surgical complications. Procalcitonin (PCT), C-Reactive-Protein (CRP) and Lactate have been used as predictor of infectious complication in surgery. The aim of this study is to evaluate the role of the combination of PCT, CRP and Lactate in predicting complications after colonic surgeries.

2 - Methods

A) Summary

Multicentric prospective study of consecutive patients undergoing any colonic operation with primary anastomosis, and without protective stoma. The aim of the study is to enroll at least 1000 patients starting in January 2015. All patients will be followed for 30 days post-operation.
No change to normal patient management is required.

B) Primary Objective

To explore the predictive value of PCT, CRP and Lactate, for post-operative complications.

C) Primary Research Question (should this be required for local approvals process)

Do PCT, CRP and Lactate values, alone or in combination offer a valuable method of prediction of post-operative complications?

D) Inclusion Criteria

- All adult patients undergoing colonic resection with primary ileocolic or colocolic anastomosis, at a participating hospital during the study period.
- All adult patients undergoing colonic resection with primary colorectal anastomosis only if the anastomosis is above the peritoneal reflexion, at a participating hospital during the study period.
- All operations of this type are included, for any pathology excluded IBD, via any operative approach and only in the elective settings

E) Exclusion Criteria

- Patients not undergoing primary anastomosis, or who are given a temporary defunctioning loop ileostomy
- Rectal resection for rectal diseases
- Associates procedures: multivisceral resection, liver surgery, Gynaecologic surgery, Urologic surgery
- Inflammatory Bowel Disease

F) Methods for identifying patients

Multiple methods may be used according to local circumstances/staffing.

G) Centre eligibility

All hospitals/units performing colon surgery are eligible to join this study.
No unit size or case throughput stipulations are made.
All participating centres will be required to register their details with the study coordinators and will be responsible for their own local approvals process prior to the start of the data collection period.
Centres should ensure that they have appropriate pathways and manpower to include all consecutive eligible patients during the study period and provide >95% completeness of data entry.

H) Patient follow-up

The audit is designed so normal patient follow-up pathways can be utilized to obtain outcomes data. No additional visits or changes to normal follow-up should be made.
Clavien-Dindo classification of complications will be used.
The follow up required is 30 days from the date of the operation.

I) Study flow sheet

Blood samples should be collected at 24h (24 ± 3h), 48h (48 ± 3h) and 72 (72 ± 3h) after the finishing hour of the surgery. We consider acceptable a tolerance of 3h.
In case of complication the blood samples should be collected as they are diagnosed
Please see section 3 for the study flow-chart.

J) Data completion and organization

This research takes the form of data collection, and no changes to the normal patient pathway need to be instigated for it to be run.
The completion of the database is responsibility of the Centres' referees: data accuracy and completeness are of paramount importance.

K) Missing data

Any missing or erroneous data can be altered by the local investigators whilst the data collection period is ongoing. In order to maximize data completion and emphasize its importance to collaborators, participating centres with >5% missing data fields (ie less than 95% data completeness) will be excluded from the study.

L) Data collection system and information governance

Data will be recorded contemporaneously and collated on a dedicated database. No personal data that can identify the individual patient (name, social security number, date of birth, address…etc.) will be needed or recorded. Registered local investigators will receive a copy of the database and will have always access to all of their unit's data.
During the study period, units will use a local identification number (of their own choice) to identify each individual patient and allow re-accessing of an individual's records to update on progress, complications etc., whilst also preventing duplication of patient entry to the study. This local identifier will be automatically permanently removed from the database prior to data analysis. The data may be used for future research although it should be noted that the anonymised nature of the database means individual patients will not be reverse-identifiable in the future.

M) Local approvals

All data collected will measure current practice, with no changes made to normal treatment. As such, this study should be registered as an audit of current practice in each participating centre. It is the responsibility of the local team at each site to ensure that local audit approval (or equivalent) is completed for their centre. Participating centres will be asked to confirm that they have gained formal approval at their site.

N) Authorship

A maximum of 5 investigators from each individual site will be included as formal co-investigators in this research, and will be Pubmed searchable and citable. They will be recognized as under a single corporate authorship - e.g. "ProcaGroup" or similar.

P) Publication of data

The primary aim of this project is to explore the usefulness of PCT, CRP and Lactate in detecting post-operative complication in colonic surgeries.

As such, the majority of data will be published as a collated pool from all participating units.
Subgroup analyses by disease, technique or outcome variables may be presented, but no hospital-level or surgeon-level data will be published whereby an individual unit or surgeon could be identified.
If local investigators would like a breakdown of their own unit's data for benchmarking purposes and local presentation/discussion, this will be provided upon request.

Q) Financial arrangements

This study is run by the coordinators, who have made the database and will assume the burden of data analysis.
No registration fee is payable by units to join the project or to enter data online.
Similarly, no financial reimbursement will be made to units or investigators for their involvement in the project.

3) Study flow sheet showing patient pathway and Study pathway