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Risk of bacteremia in banding versus sclerotherapy of esophageal varices

Submission date
05/09/2014

Recruitment status
No longer recruiting

Registration date
22/09/2014

Overall study status
Completed

Last Edited
16/10/2019

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Esophageal varices (EV) is a condition where the blood vessels in the esophagus are extremely dilated (widened). Banding is a treatment that uses elastic bands to tie the blood vessels in order to stop bleeding. The other treatment available for this condition is sclerotherapy, where a medicine is injected which will cause the blood vessels to shrink. Esophageal variceal banding may be less likely to cause bacteremia (occurrence of bacteria in the blood) than sclerotherapy. We do not know how frequently bacteremia occurs after banding or sclerotherapy. We conducted this study to compare the frequency of bacteremia after banding and sclerotherapy.

Who can participate?
Patients with liver disease admitted for upper gastrointestinal bleeding or those who came for variceal therapy who have had previous treatment for EV.

What does the study involve?
Those who came as an outpatient for elective sclerotherapy or banding were given their preferred treatment. New patients with upper GI bleeding were checked by endoscopy before any treatment. Those who required treatment were randomly allocated to either undergo either banding or sclerotherapy. Those who did not need treatment were considered as the control group. Blood samples of all patients were analysed at 5 and 30 minutes to check for bacteremia.

What are the possible benefits and risks of participating?
There were no financial benefits of participating in this study. Patients received treatment for esophageal varices. There were no obvious risks.

Where is the study run from?
Thomason General Hospital in El Paso, Texas, USA.

When is the study starting and how long is it expected to run for?
July 1995 to April 1997.

Who is funding the study?
Investigator initiated and funded (USA).

Who is the main contact?
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Contact information

Type(s)
Scientific

Contact name
Prof Marc Zuckerman

Contact details
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El Paso
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79905

Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
A prospective randomized study on the risk of bacteremia in banding versus sclerotherapy of esophageal varices

Study objectives
After endoscopic variceal ligation (EVL) was introduced, we designed this prospective randomized study to compare the rate of bacteremia after endoscopic esophageal variceal ligation with that of sclerotherapy.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Texas Tech University Health Sciences Center Institutional Review Board, 03/16/1993

Study design
Prospective randomized study in single center done before to register retrospective clinical study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Bacteremia in patients with liver disease admitted for UGI bleeding

Interventions
All patients were screened using endoscopy.
Outpatients for vacricela therapy to undergo: banding or sclerotherapy.

Patients with upper GI bleeding were randomised to:
1. Banding
2. Sclerotherapy

Blood cultures were obtained before, 5 and 30 minutes after endoscopy to check for bacteremia.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Blood cultures were drawn via separate venous punctures of the forearm before endoscopy (BCX1), at 5 minutes (BCX2), and 30 minutes (BCX3) after the endoscopy.

Key secondary outcome(s))
Continuous data were described using mean and standard deviation (SD) while categorical data were described frequency and proportion. Baseline characteristics were compared among groups. Continuous data were compared using one-way analysis of variance (ANOVA), while categorical data were compared using Fishers exact test.

Completion date
01/04/1997

Eligibility

Key inclusion criteria
Patients with liver disease admitted for UGI bleeding or for outpatient elective variceal therapy with previous EVS and EVL at Thomason General Hospital in El Paso, Texas, from July 1995 to April 1997

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
94

Key exclusion criteria
Patients were excluded if they had received any antibiotics in the last 2 weeks before inclusion in the study

Date of first enrolment
01/07/1995

Date of final enrolment
01/04/1997

Locations

Countries of recruitment
United States of America

Study participating centre
Division of Gastroenterology
El Paso
United States of America
79905

Sponsor information

Organisation
Texas Tech University Health Sciences Center (USA)

ROR
https://ror.org/033ztpr93

Funder(s)

Funder type
Other

Funder Name

Investigator initiated and funded (USA)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	02/05/2016	16/10/2019	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes