CRITICAL ANALYSIS

Introduction

Diabetes type 2 is the **most common diabetic disease** in the world, making up 95% of diabetic conditions among adults.

Obesity increases risk of diabetes type 2 by **80-85%** by aggravating insulin resistance from stress on the endoplasmic reticulum.

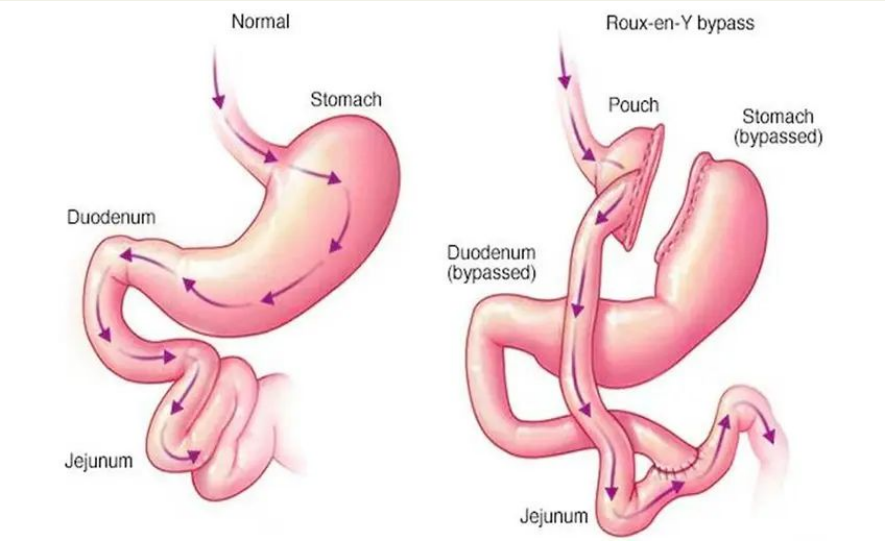
Definitions

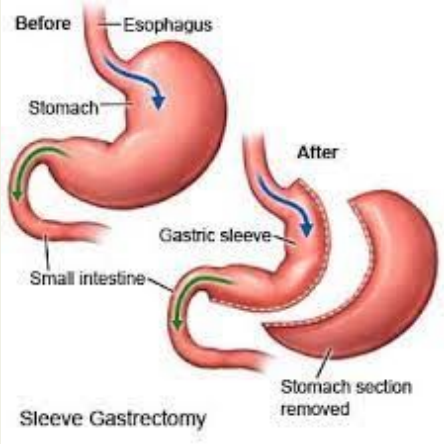
Gastric bypass with Roux en Y

- A procedure where the stomach is divided, then a gastric pouch is made from one of the parts, which is connected to the jejunum. Roux En Y is used to connect the bypassed duodenum to the jejunum to ensure sufficient bile flow.

Sleeve gastrectomy

- Removal of the greater curvature of the stomach to create a small gastric sleeve.





Indications

Indications:

- BMI 35-40 with comorbid diseases associated with obesity
- Failure to treat obesity non surgically
- Mentally stable
- Not contraindicated to anaesthesia/surgery
- Willing to follow up visits, diet control and medication compliance

Contraindications

Contraindications:

- Any patient who is unable to understand the surgical procedure
- BMI less than 30 or obesity is secondary to another disease
- Psychiatric disorders
- Severe illnesses including ESRD
- Unique to sleeve gastrectomy: Barrett's esophagus or GERD

Clinical Relevance

- **JAMA surgery publication** - recent and up to date
- Only study addressing this research question with a **large sample size**
- **Mixed outcomes** of bariatric surgery to diabetes: one quarter to a half of the participants have a relapse
- **Limited long term comparative data** between roux en y and sleeve gastrectomy to justify the preference for roux en y gastric bypass to sleeve gastrectomy

Author

Kathleen M. McTigue, MD; Robert Wellman, MS; Elizabeth Nauman, MPH, PhD; Jane Anau, BS; R. Yates Coley, PhD; Alberto Odor, MD; Julie Tice, MS; Karen J. Coleman, PhD; Anita Courcoulas, MD; Roy E. Pardee, JD; Sengwee Toh, ScD; Cheri D. Janning, MS; Neely Williams, MDiv; Andrea Cook, PhD; Jessica L. Sturtevant, MS; Casie Horgan, MPH; David Arterburn, MD; for the PCORnet Bariatric Study Collaborative

a. Researchers from **different institutes of America**
b. **Balanced amount** of surgery and clinical medicine researchers
c. **Conflicts of interest**
    i. Dr Courcoulas reports grants from Covidien/Ethicon Johnson & Johnson, during the conduct of the study.
    ii. Dr Tavakkoli reports personal fees from Medtronic and AMAG pharmaceuticals.
    iii. Dr Jones reports personal fees from Allurion. Mr Nadglowski reports other support from the Obesity Action Coalition outside the submitted work
d. **Funding**
    i. funded by the Patient-Centered Outcomes Research Institute

- The funder **did not have a role in the study design**; in the collection, management, analysis, and interpretation of data; in the preparation, review, or approval of the manuscript; and in the decision to submit the manuscript for publication.

Journal

- **Impact Factor of 14.8**, highest ranking surgery journal
- Over **3.4 million** annual visits
- Top Altmetric scores—JAMA Surgery published **24 of the top 50** articles among general surgery journals
- Highly selective peer review and editorial evaluation, with **12% acceptance rate** for all submissions

PICO & Hypothesis

PICO

- P = T2DM patients
- I & C = Roux-en-Y gastric bypass (RYGB) or sleeve gastrectomy (SG)
- O = Type 2 diabetes remission

Aim

1. To examine and compare the 5-Year Diabetes Outcomes between Sleeve Gastrectomy and Gastric Bypass on type 2 diabetes remission in patients with T2DM

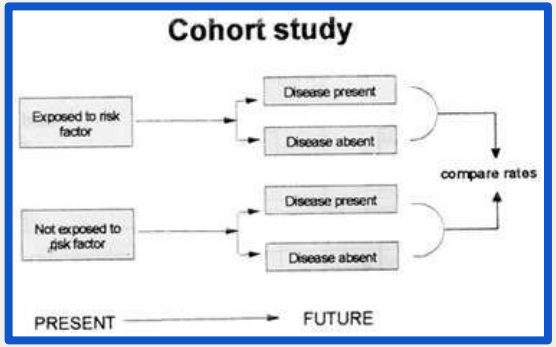
Hypothesis & Null hypothesis

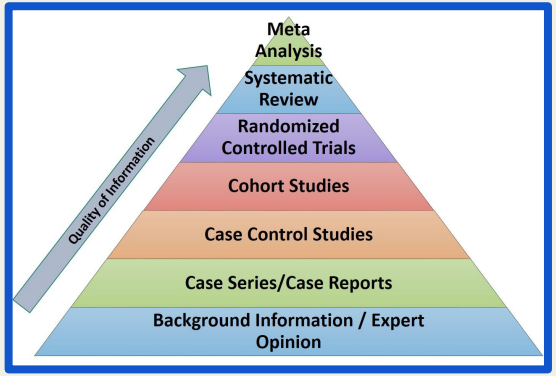
2. Not stated

Study Design

Retrospective Cohort Study - 5 year follow up

- **Strong** level of evidence, just below RCTs
- RCTs **not appropriate** here as its a surgical intervention, double blinding not able to be implemented, unethical to subject participants to surgical intervention
- Diabetes remission involves other factors like lifestyle, compliance to medication. Detailed baseline information on lifestyle and exposure collected from each and they are followed over time
- Allow for **larger sample size**





Strength & Limitation

Strengths

- Large sample size
  - 9710 patients
  - Especially when compared to previous RCTs
    - Can generalize
- Multicentered
  - Reduce confounders
- Follow up of 5 years
- Strong level of evidence
  - below RCT

Limitations

- Shorter follow up compared to previous RCTS
- Observational
  - Confounders→hard to determine the relationship
  - Not the highest in the evidence pyramid
- Using ICD 9 coding
  - Underestimated comorbidity
- Pbs definition → Relapse and remission relies on medication prescription data
  - Ordered outside the health system
  - No meds
  - Undiagnosed dm is really common,might have only dx preop
- All dates were normalized to the date of surgery
  - cannot differentiate finish and dropped out → attrition bias

Evaluation of Study

Reliability of the Study

- Are the results statistically significant?
  - Yes they are!
  - P-value < 0.001 except the remission of T2DM. (P = 0.007)

Primary outcome	Secondary outcomes
Remission of Type 2 Diabetes Mellitus	Total weight loss percentages
	Time taken for T2DM relapse
	Changes in Hba1c in 6 months, 1 year, 3 years and 5 years

Evaluation of Study

Were all outcomes considered?Were all outcomes considered?

Outcomes not considered

- End organ damage
- Morbidity
- Mortality
- Survival rate
- Complications of surgery

Applicable to Malaysia?

Is this study applicable to our demographic?

- T2DM prevalence in Malaysia is high + disease burden (mortality + morbidity)
- It's an option for poorly managed DM here in Malaysia
- Potentially cost effective
    - Surgical costs vs Medical costs in the long term
- Management perioperatively as well as post-op is similar

Issues

- Availability of resources & expertise
- Large majority of patient population in this study are not Asian (not using Asian BMI, potential population differences, didn't focus on ethnicity difference)
- Possible differences in management of DM
    - Different cut-off points for target blood sugar
        - FBS (America): 4.4-7.2 mmol/L, Post-prandial: < 10 mmol/L
        - FBS (Malaysia): 4.4-7.0 mmol/L, Post-prandial: 4.4-8.5 mmol/L, HBA1C same for both countries -> < 7.0%

Conclusion

From Jiménez et al. (2012), roux-en-Y gastric bypass and SG are associated with **comparable remission rates of T2DM**. (prospective cohort study)

- **75.2%** of subjects presented with remission of T2DM lasting at least 12 months.

From Lee et al. (2011), participants randomized to gastric bypass were **more likely to achieve remission of T2DM**.

- **28/30 - 93%** of patients achieved remission of T2DM after a 12 month follow-up

Future Prospects of Research

- Bariatric surgery may be suitable for some patients with the right profiles
- Studies need to focus on long-term morbidity as well as cost effectiveness of bariatric surgery on DM

Thanks!

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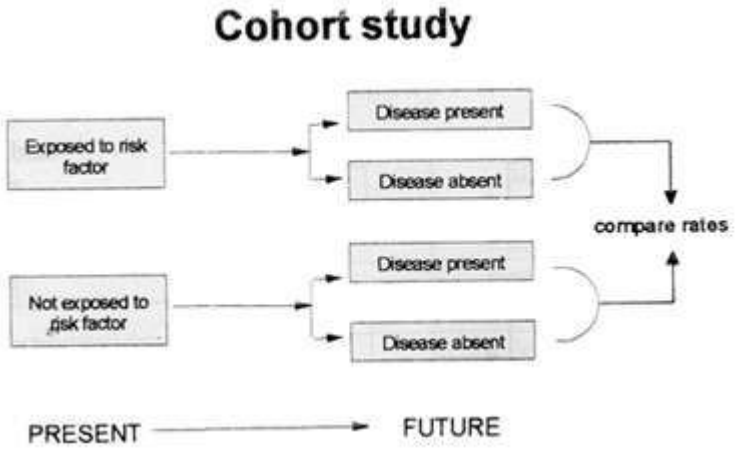

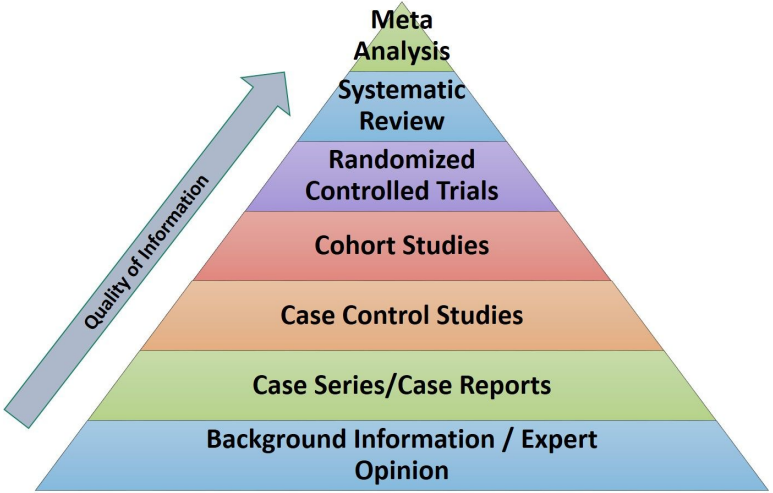

Strengths

- Large sample size
  - 9710 patients
  - Especially when compared to previous RCTs
    - Allow generalizing all dr and patient especially since they stratify across multiple factors
- Multicentered→ less likely there is dr factor and hospital protocol things
- Decent followup of 5 years
- Strong level of evidence below rct

Limitation

- Not the highest inthe evidence pyramid
- Shorter followup compared to previous RCTS
- Observational
  - Procedure might be affected by unmeasured factors that affect the surgery
  - Also harder to determine the relationship
- Using ICD 9 coding
  - Underestimated comorbidity?
- Pbs definition → Relapse and remission relies on medication prescription data
  - Ordered outside the health system
  - Undiagnosed dm is really common
- All dates were normalized to the date of surgery
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- Prone to confounders
- Participants and researchers are not blinded

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- It is a treatment option for poorly managed DM here in Malaysia
- Potentially effective to put DM into remission (reduce costs)
    - Surgical costs vs Medical costs in the long term
- Management perioperatively as well as post-op is similar [ERABS (enhanced recovery after bariatric surgery pathway)]

Issues:

- Availability of resources & expertise
- Large majority of patient population in this study are not Asian (not using Asian BMI, potential population differences, didn't focus on ethnicity difference)
- Possible differences in management of DM
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What are the implications to future clinical practice?

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