Surgery

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A pilot double-blind randomised controlled trial for high-dose intravenous zinc as adjunctive therapy in SARS-CoV-2 (COVID-19) positive critically ill patients.

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Introduction: Elemental zinc has previously been demonstrated to have beneficial effects on coronaviruses and other viral respiratory infections due to its effect on RNA polymerase. Zinc is a potent inhibitor of the replication of SARS-coronavirus (SARS-CoV) and equine arteritis virus in cell culture. Zinc deficiency results in reduced immunity and increases susceptibility to infectious diseases. Our published studies have shown that high-dose intravenous zinc chloride (HDIVZn) protects various organs, including the heart, kidneys and liver against the damage caused by hypoxia—a clear mechanism of end-organ injury in COVID-19. We aimed to evaluate the safety, feasibility, and efficacy of administering HDIVZn to patients with COVID-19.

Methods: We designed a double-blind randomised controlled phase II trial of daily HDIVZn (0.5mg/kg as ZnCl) versus placebo (normal saline). Primary outcome measures were safety profiles with respect to local symptoms, renal, hepatic, gastrointestinal, cardiac and haematologic domains. We administered trial treatment once daily for a maximum of seven days until either death or hospital discharge. We measured zinc concentration at baseline and during treatment and observed patients for any significant side effects.

Results: We randomised and administered treatment to 33 adult participants to either HDIVZn (n=15) or placebo (n=18). We observed no serious adverse events throughout the study for a total of 94 HDIVZn administrations. However, 3 participants in the HDIVZn group reported infusion site irritation. Mean serum zinc on day 1 in the placebo, and the HDIVZn group was 6.9 ± 1.1 and 7.7 ± 1.6 µmol/l, respectively, consistent with zinc deficiency. HDIVZn, but not placebo, increased serum zinc levels above the deficiency cut off of 10.7 µmol/l ($P<0.001$) by day 6. Using the KDIGO criteria for Acute Kidney Injury, no patients in either arm suffered a Stage 1, 2 or 3 renal injury. Our study did not reach its target enrolment for efficacy outcomes because stringent public health measures markedly reduced patient hospitalisations.

Conclusion: Hospitalised COVID-19 patients demonstrated zinc deficiency. This can be corrected with HDIVZn. Such treatment appears safe, feasible and only associated with minimal peripheral infusion site irritation likely because of the acidic nature of the HDIVZn preparation. This pilot study justifies further investigation of this treatment in COVID-19 patients.

Trial Registration: Clinical trial registered with Australian New Zealand Clinical Trials Registry (ACTRN126200000454976). No external funding was provided for the completion of this project.

Evaluation of Outcome Measurement Tools in Patients with Lymphoedema

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Topic: Measuring quality of life in patients with lymphoedema

Introduction
Lymphoedema can significantly affect patients' quality of life. Multiple health related quality of life (HRQOL) instruments have been used in lymphoedema studies, however there is currently no standardised tool [1]. The use of a standardised instrument is vital in lymphoedema research to assess the impact of lymphoedema on patients, demonstrate change as a result of treatment and assess the effectiveness of different interventions. The aim of our study is to review the types of HRQOL measures used in the studies of lymphodema and identify the best HRQOL instrument tool that should be used in clinical setting and research.

Methodology
Systematic literature review was conducted in Pubmed from 1984 to 2020. Pubmed database was searched to identify lymphoedema studies that involve the use of HRQoL measurement tools. HRQoL questionnaires were then extracted from these lymphoedema studies.

Results
39 questionnaires to evaluate HRQoL in patients with lymphoedema were found in the English literature. Out of the 12 lymphoedema-specific tools, LYMQOL [2] and ULL-27 [3] were found to be most comprehensive and reliable with good validity.

Conclusion
We recommend the use of LYMQOL and ULL-27 routinely to assess HRQoL in lymphoedema to allow an objective comparison between effect of different treatments.

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Cox DRA [1,2,3], Wong BKL [3,4], Zhang F [3], Mehmed T [5], Mathivanan S [4], Ellis S [6], Jones R [1,2,7], Do H [5], Testro A [7], Muralidharan V [1,2], Dobrovic A [3,4].

Determining the relative contributors of circulating mitochondrial-derived cell-free DNA in human plasma.

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Aim: To quantify levels of circulating, mitochondria-derived cell-free DNA (cmtDNA) in human plasma with respect its variable origins.

Methods: Human research ethics committee approval was obtained. Figure 1. provides a summary of the study workflow. Blood was taken from 21 healthy volunteers. A plasma processing protocol was developed that, through differential centrifugation and filtration, enabled the removal of various contributors of cmtDNA in a step-wise fashion from human plasma. Droplet digital PCR (ddPCR) was used to quantify levels of cmtDNA in the plasma aliquots. Confocal microscopy, transmission electron microscopy and flow-cytometry were used to demonstrate step-wise removal of the various contributors of cmtDNA from the plasma aliquots.

Results: Using a "subtraction technique", cmtDNA quantification through ddPCR enabled the estimation of the relative contributions of various plasma components to total measured cmtDNA. On average, in plasma samples from this healthy cohort: 68% of the total measured plasma cmtDNA originated from platelets, 27% from circulating, cell-free mitochondria, 3% from extracellular vesicles and 2% as un-encapsulated cell-free DNA.

Discussion: There is growing interest in the analysis of cmtDNA in molecular diagnostics. Elevated levels of plasma cmtDNA have been linked to the development of the systemic inflammatory response syndrome (SIRS) following injury (e.g. post-surgery or trauma). cmtDNA is present in the plasma in different forms, relating to its variable origins. Previous studies linking elevated cmtDNA levels and SIRS following tissue injury have quantified *total plasma cmtDNA* irrespective of its potential origins or presentation in the plasma. We have developed an evidence-based sample processing technique to quantify cmtDNA with respect to its various contributors. This technique will enable further clinical investigation into the association between elevated cmtDNA levels and the development of SIRS. Understanding the origins of cmtDNA may assist in investigating the mechanisms behind the action of cmtDNA as a "damage associated molecular pattern".

Figure 1. Study workflow summary schematic.

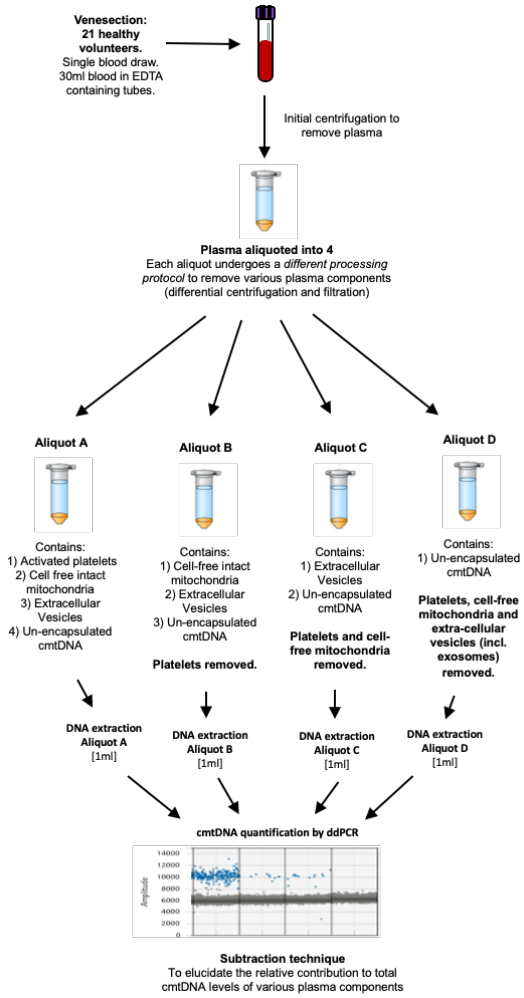
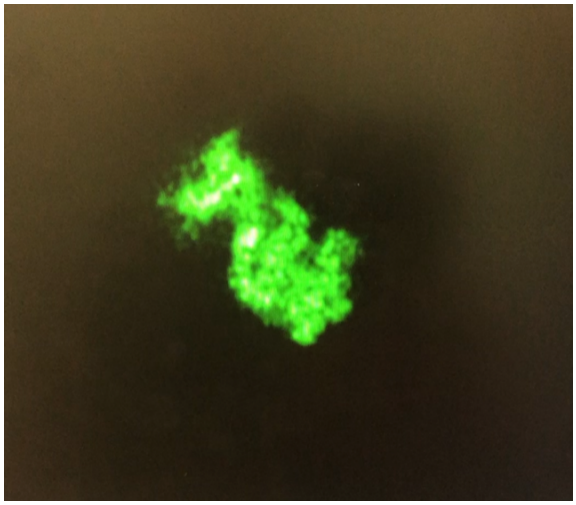


Figure 2. An intact, cell-free mitochondrion: in human plasma treated as per "Fraction B" protocol. Method: Confocal laser microscopy, fluorescence stain: MitoTracker™ Green FM (Thermofisher, Waltham, MAS).



Boynes A[1], Khong JJ[1,2], Hardy T[2], Enright N[2]

Comparison of specialist and trainee accuracy in assessing TED using VISA grading

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Background
Thyroid eye disease (TED) is an autoimmune disorder causing inflammation, expansion and fibrosis of orbital fat, muscle, and lacrimal gland. One of the challenges of TED is how to classify and grade its various clinical manifestations. The VISA classification system categorizes four specific end points of TED (vision, inflammation, strabismus, and appearance/exposure) and summarizes these in a clinical form useful for grading specific subjective and objective measurements and for guiding management. Therefore, reliable measurement of grading the clinical manifestations is essential.

Purpose
The purpose of this study is to determine the accuracy of photographic assessment of TED with the VISA classification system using an online survey. We will compare the reliability of assessment between oculoplastic subspecialists, general ophthalmologists, and ophthalmology registrars. In addition to this we will assess whether a TED atlas improves registrar performance in assessing photographs of TED.

Methods
We will email participants a 5-minute online survey asking them to grade 10 photos of TED. Participants will include international and interstate practitioners via the Royal Australia and New Zealand College of Ophthalmologists (RANZCO), Australian and New Zealand Society of Ophthalmic Plastics Surgeons (ANZSOPS) and affiliated ophthalmic plastic surgeons' membership society internationally. A TED grading atlas by the European Group on Graves Orbitopathy (EUGOGO) will be provided to 50% of the ophthalmology registrars participating in the study. Participants will be given 1-month after receiving the survey to respond. Inter-rater reliability will be analysed by percentage agreement and kappa scores and be compared between groups of practitioners by their level of experience. Additionally, the effect on clinical performance with the provision of a training atlas will be compared in the registrar cohort.

Conclusions
Previous studies have shown significant inter-rater and intra-rater variability in grading TED using the VISA system. This study aims to determine whether the VISA grading system is reliable in assessing TED; whether there is significant inter-rater reliability depending on level of expertise; and if the use of a grading atlas improves registrar reliability in grading TED.

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Experience with NovoSorb® Biodegradable Temporising Matrix in reconstruction of complex wounds

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Aim
The NovoSorb® Biodegradable Temporising Matrix (BTM) is a synthetic polyurethane dermal matrix used to reconstruct complex wounds including deep dermal and full thickness burns, necrotising fasciitis and free flap donor site. We hope to further explore its potential applications in this series.

Methods
Patients who received BTM application across four centres over an 18-month period were included. Patients were followed up to assess BTM and graft take, the aesthetic, the return of sensation and complications.

Results
A total of 27 patients with 35 wounds were identified with a range of aetiologies. 33 wounds had 100% integration of BTM at the time of sealing membrane removal. Seven wounds had partial graft loss that later healed by secondary intention. In two cases re-epithelialisation occurred with BTM alone without split skin graft.

Conclusion
BTM offers a safe and reliable reconstructive option in challenging wounds that would otherwise require more complex operations.

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R. NEWBOLD[1], A. CRAVEN[1], A. ALY[1]

Efficacy of patient selection criteria for obesity surgery in a non-HDU/ICU facility.

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AIM
Publicly funded obesity surgery remains underfunded in Australia. One barrier to expansion is the perception that perioperative care requires critical care facilities. This study evaluates the effectiveness of patient selection criteria in avoiding unplanned patient transfer and adverse outcomes in obesity surgery performed at a facility without an HDU/ICU.

METHODS
Retrospective analysis was performed on patients undergoing obesity surgery between January 2017 to March 2020 in a centre with specific screening criteria. Criteria included: BMI <48 for males and <52 for females with up to three stable comorbidities from a selected list. Revision sleeve or bypass procedures were contraindicated. Primary outcome was patient transfer to our main campus. Secondary outcomes included return to theatre (RTT), readmission and death. Outcomes were compared to laparoscopic cholecystectomies (LC) performed at the same centre.

RESULTS
387 obesity surgery procedures were performed. 372 patients (96%) were discharged without complication. 15 (3.9%) were transferred to the main campus, 8 were admitted to ICU and 2 required re-operation. 12 (3.1%) were readmitted within 30 days of discharge, 5 required re-operation. Transfer, 30 day readmission, and 30 day ED presentation rates were similar in comparison to LC. RTT during index admission (0.5% versus 3.0%; P = .006) and during 30 day post operative period (1.8% versus 4.4%; *P* = 0.025) was lower in the obesity surgery group.

CONCLUSION
Carefully selected screening criteria allow obesity surgery to be performed at a well supported non-HDU/ICU facility with few complications and acceptable rates of unplanned patient transfer.