EDITORIAL

REBOA: Where are we now?

In this edition, a group from The Alfred in Melbourne publish their experience with Resuscitative Endovascular Balloon Occlusion of the Aorta (REBOA). The paper highlights the challenges with setting up clinical trials in critical care patients, especially for interventions that are ‘high acuity, high consequence, low frequency’. Despite considerable effort into generating a protocol and eligibility criteria, the Melbourne group were able to site only one REBOA catheter during the trial period and that was in a patient later found to be ineligible. Exploration of the patient groups showed that most patients were either in cardiac arrest or in peri-arrest when they were enrolled. Although the results add little to the overall REBOA literature, it does suggest that patient selection may be the real key to REBOA and that this requires a good deal of more data to clarify.

The principles and history of REBOA are well known and the concept of balloon occlusion is not new to interventional radiologists and vascular surgeons. In fact, balloons are inflated in the vascular tree in a variety of situations, including trauma, post-partum haemorrhage, aneurysm management and myocardial disease. Patient selection, time to inflation and the time of inflation/occlusion are the key parameters. Specialist clinicians will continue to perform balloon occlusion in these situations; however, the recent spotlight on REBOA in acute exsanguinating non-compressible haemorrhage and in particular the advent of REBOA through a 7-Fr sheath has opened the door to earlier balloon placement in a cohort that were previously thought to be ‘too late’ for the intervention.

It is clear that balloon occlusion is an undisguised attempt to buy time for a dying patient while definitive care is sourced/arranged/commenced. The question now being asked is whether exsanguinating trauma patients could or should be getting balloon occlusion earlier? For this to happen appropriately, balloon occlusion needs to be carried out by the clinicians who are by the patient’s side at the critical moment that benefit is thought to outweigh risk. These clinicians are mostly (but far from exclusively) pre-hospital and retrieval specialists, emergency physicians and general/trauma surgeons. In our institution, a few critically exsanguinating trauma patients will get an ED thoracotomy solely for external aortic occlusion (AO) while they are rapidly moved to theatre for definitive surgical care. But is either method of AO (ED thoracotomy or REBOA) any better than wheeling the patient to theatre under CPR? Biological plausibility might suggest so but there is no confirmatory evidence. To complicate matters further, how do we ‘buy time’ for the exsanguinating trauma patient injured a 30 minute helicopter flight away from the trauma centre?

So there is a gap in care for the acute exsanguinating trauma patient with non-compressible haemorrhage and REBOA is a tempting solution. But does it work? The evidence is not plentiful and what is there is far from clear. In the absence of randomised controlled trials, the REBOA literature has largely remained occupied by reviews, data trawls, ‘meta-analysis’ and consensus reports or statements. Although much of this published data suggest a positive influence of REBOA, there is likely to be a degree of publication bias.

A 20-year review from France strongly supported REBOA. Similar support came from a trauma centre in Florida and yet another from Baltimore. In the pre-hospital world there has been success in London and data from France suggest 3% of trauma patients (over 1000 per annum) could be eligible for REBOA. The military also describe impressive and successful case reports. A meta-analysis of REBOA and another of REBOA and open aortic cross clamping together with an early REBOA registry report all suggested positive effects on outcomes and are broadly supportive. There followed a statement from the American College of Surgeons highlighting indications, guidelines and complications. This statement has been recently updated and offers an excellent synopsis of key issues when considering utilisation of REBOA. Another paper presented a Delphi consensus statement covering similar aspects of REBOA.

However, a recent national analysis from the United States seemed to suggest harm from REBOA and although the paper certainly caused an appropriate pause in growing groundswell of pro-REBOA opinion, the paper was far from being the high-quality evidence required. This was pointed out in well-publicised responses. Furthermore, another more recent matched database review from Japan seems to contradict the US data and has demonstrated improved survival with REBOA. The potential for REBOA to cause harm can come as a surprise to no one, but the facts are muddied by several issues. The device itself continues to evolve and crucially can now be inserted through a much smaller sheath (7-Fr vs 12-Fr) which may lead to fewer complications. In addition, with all the publicity, publications and statements of recent years, the procedure itself is evolving as are the clinicians performing it. This can only improve techniques and skills as well as ‘post procedure care’ for the patients who have had REBOA performed on them.

Other new areas under evolution include partial REBOA and intermittent REBOA whereby the balloon is only part inflated or undergoes inflation and deflation cycles. Add to this the novel concept that REBOA is in fact a spectrum of technology whereby common femoral artery access is achieved early either with a 7-Fr (or maybe even a 5-Fr with a view to upsizing) and...
used for initial monitoring. Subsequently the sheath can also be used for interventional radiology, for REBOA or even for extracorporeal membrane oxygenation if required. On balance, it is becoming increasingly difficult to look at data from even 5 years ago and meaningfully compare it to current practice.

Supporting this is the most recent data from the latest American Association for the Surgery of Trauma meeting, suggesting a clear survival advantage with REBOA in bleeding pelvic trauma patients.21 Interestingly a poster from the same conference highlighted that AO in trauma patients was best done sooner rather than later and waiting for the systolic BP to drop to below 70 mmHg might be too late.22 The Melbourne study had a systolic BP of less than 70 mmHg as part of its eligibility criteria, which may have contributed to its poor recruitment rates and results.

Unsurprisingly and rather disappointingly what is required once again is the now tired statement of ‘a well conducted randomised control trial comparing current REBOA techniques with current standards of care’. Such a trial would need careful patient selection with meticulous inclusion and exclusion criteria and an intense focus on timing. The current UK-REBOA randomised control trial23 looking to recruit 120 patients across 10 major trauma centres may go some way to meeting this objective. This brings us full circle to the Melbourne paper, which has nicely demonstrated that even with the best will in the world, trials on high acuity, high consequence, low frequency interventions such as REBOA are incredibly difficult to conduct and The Alfred group is to be commended for trying.

Competing interests
None declared.

References
time-to-put-the-reboa-balloon-away-maybe-maybe-not/


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