AOA SUBMISSION

Draft: *Venous Thromboembolism Prevention Clinical Care Standard*

30 September 2017

AOA
AUSTRALIAN ORTHOPAEDIC ASSOCIATION

The Australian Orthopaedic Association (AOA) welcomes the opportunity to submit a response regarding the Australian Commission on Safety and Quality in Health Care's draft *Venous Thromboembolism Prevention Clinical Care Standard (September 2017)*.

The Australian Orthopaedic Association is the peak professional body for orthopaedic surgeons in Australia. AOA provides high quality specialist education, training and continuing professional development. AOA is committed to ensuring the highest possible standard of orthopaedic care and is the leading authority in the provision of orthopaedic information to the community.

AOA has sought advice from its specialty societies and provides the following feedback.

VTE Clinical Care Standard Clinician Fact Sheet

The clinical care fact sheet is satisfactory, bearing in mind that all these sheets are overly long and repetitive to an extent which would suggest that very few people other than lawyers will ever read them.

On page 8 of VTE prevention (VTE-Clinical-care-Standard-Consultation-draft) is the statement: "While DOACs can be given orally and do not require routine laboratory coagulation tests to monitor therapeutic effect, monitoring adherence and managing thrombotic events is more difficult in patients taking these medicines." It is AOA's understanding is that this is not the case for dabigotran and that this drug needs monitoring to appropriately control its levels. It is not just a standard dosage (per size etc.) as are the oral Xa inhibitors. Dabigotran monitoring, is not the same as other DOACS.

Another factor, which may be only true of public hospitals, is the implication of the transfer of care to a general practitioner. Generally, the general practitioner will know less about VTE prophylaxis than the surgeon. Also, in the private sector, one would not anticipate any contact with the general practitioner for this sort of treatment during the immediate follow up period (as determined by the MBS rules). This would seem to be the responsibility of the surgeon. Hence, only if the patient has a need to see the general practitioner (if the patient is from out of town or from a rural/remote area etc.) then transference of relevant information may be required. In most cases however, provision of relevant VTE information, as part of the letter to the general practitioner about their surgery, should suffice and this may take more than mandated 48 hours to arrive. Legal ramifications for 'failure of notification' on time are important.

VTE Clinical Care Standard Consumer Fact Sheet

The VTE-Clinical-Care-Standard-Consumer-Fact-Sheet-Consultation-Draft suggests that "A patient at risk of VTE receives information and education about VTE and ways to prevent it tailored to their risk and needs, and shares in decisions regarding their VTE prevention plan." This approach is fine in theory, but standardised regimes are better than creating new regimes for each individual based on patient preferences. The surgeon is best placed to make clinical decisions based on several factors including the facts gleaned, surgical knowledge, expertise and where required

consultation with other relevant specialists (cardiologist for example). Patients should, of course, be provided with all the reasons for the treatment and alternatives but it must remain a clinical decision to implement a prevention program.

The document should suggest that a plan which the treating physician thinks is best practice, will be made for the patient, but that it can be discussed if necessary.

VTE Clinical Care Standards Evidence Sources

The VTE Clinical Care Standards Evidence Sources is clearly the best document. It is well considered and presents what is known (or not known). The volume and comprehensiveness of the review are impressive and the conclusions seem balanced.

General Comments

Information to Patients from these documents appear to be lacking in two areas:

- There is no reference to venous thromboses that are not deep (DVT's). Patients assume that all calf thromboses are DVT's which is not the case. This requires a definition and an associated risk description so that: if one elects not to treat a Non-Deep VT in the manner described for a DVT, then the patient should know that the risk is very different, and that therefore, the risk benefit ratio is also different. This is a very important explanation for the patient to alleviate what is often a worrying time for them.
- Pulmonary embolus (PE) risk is never dealt with directly. The general assumption which these documents imply is that, by reducing the incidence DVT's, there will be a commensurate reduction in the incidence of PEs. Unfortunately, this is untrue, and there is no literature evidence of which AOA is aware of that suggests that a PE can be prevented by standard low dose (non-fully anti-coagulating) prophylaxis. Symptomatic DVT's are those where, mostly, the clot sticks to the wall of the vein and causes phlebitis. PE's often have no detectable DVT suggesting that the clot does not stick to the wall, and hence travels directly to the lung with no leg symptoms or signs. It is thus a different problem, and one that may be more common than we suspect (as CTPA studies tend to suggest). It should be made abundantly clear therefore, that whereas the DVT rate can be reduced by the versions of prophylaxis that are discussed, the PE rate may be unchanged. This has very important legal ramifications in terms of blame, and hence, needs to be stated boldly in any document that allegedly empowers the patient.

Specific Comments

Arthroplasty

The direction of the recommendations appears to support the position statement of the Arthroplasty Society of Australia. Many arthroplasty surgeons use aspirin in conjunction with pneumatic calf compression +/- compressive stockings. The first

question that needs to be addressed is whether this commonly used combination has a higher or lower rate of DVT / PE (attempted review in the rapid study).

The second question to be answered is whether this combination results in less oozing, bleeding, wound haematomas and wound infections and whether “whole of patient outcomes” including morbidity of wound bleeding, haematomas and infections and DVT / PE are the same, inferior or superior.

The rapid review question to be answered was stated as:

"Is aspirin superior to other antithrombotic agents, for the primary prevention of VTE in patients who have had hip or knee replacement surgery? “

AOA would suggest that the question that needs to be addressed by a rapid review should have been:

"Is aspirin superior to other antithrombotic agents, for whole of patient outcomes including the primary prevention of VTE balanced with the known risks of anti-coagulation side effects including wound ooze, bleeding, haematomas and wound infections in patients who have had hip or knee replacement surgery?”

Of course, this is a difficult research question as there will be a paucity of well controlled studies that have addressed this question.

Sarcoma

The document has Cancer as an important indication which is accepted, although there are other potential considerations that should be able to be made to individualise care.

Cohort in Cancer: There are differences for metastatic cohort, and primary bone and soft tissue tumour cohort both of which orthopaedics looks after and sarcoma is a biological vs anatomical and vertical age specialty. The general orthopaedic community do a lot of metastatic work as well and a little bleeding from anticoagulants and liberal use of radiotherapy may not affect the limb outcome, nor the survival.

Children: It is noted the indication for use in Cancer and as vertical Specialists, our practices cover children and adults - children rarely get clots in the experience of a surgeon with 20 years of lower limb cancer surgery at a children's hospital.

Biopsy: If an initial biopsy is undertaken for example and the surgeon does their best with cementation of cavities and haemostasis. If it bleeds post-op due to the anticoagulants, risk of tumour spread inadvertently is real and may result in amputation to manage, or at least a more horrendous operation.

Resection: Operatively, patients also often given Transexamic acid to start but in a major resection, the patient may lose several blood volumes and walk a coagulopathy vs anticoagulant tightrope in the first few days.

Post operatively: If a major resection is undertaken - often leaving a large cavity that can drain a litre of serum daily for a week, we also have issues to consider with often long-term cavity drains and secondary sepsis etc as the anticoagulants affects the serum drainage.

The way forward for the tumour community is not entirely clear, in essence the surgeon must have the ability to exert clinical discretion to optimize the outcome by personalised care without feeling threatened by an algorithm, but at the same time it is accepted that the surgeon needs to do their best to avoid this potential sequalae.

The numbered days of prescribed treatment is also difficult to define and avoid tokenism for our legal protection by having prescribed a medication which maybe largely ineffective, but is defensible.

Upper limb

Upper limb surgery is generally considered low risk for VTE. Subspecialty members use anti-thrombotics on a case by case basis eg: some shoulder arthroplasty or known thrombophilia patients, but not on a routine basis.

Spine

The question regarding the patient information sheet is whether there should be a clearer statement that on occasions the increased risk of bleeding associated with chemical prophylaxis outweighs the benefit. In the spinal and neurosurgery complications are related to intracerebral bleeds, epidural haematoma etc in patients on chemical prophylaxis, while little VTE related complications.

In spine surgery the place, appropriate patients, benefit/risk ratio for chemical prophylaxis has not been clearly delineated.

Trauma

The documents do not cover orthopaedic trauma/hip fracture and it should be noted within the documents that they cannot and should not be applied to orthopaedic trauma or hip/knee fracture management.

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