

Comments on FAD Summary and NICE decision

Thoughts and comments on the decision to refuse the application for abiraterone to be used in newly-diagnosed high-risk hormone-sensitive metastatic prostate cancer in England and Wales

Patient Selection:

Hormone therapy (ADT – Androgen Deprivation Therapy) in combination with docetaxel is the current first-line therapy for newly diagnosed high-risk hormone-sensitive metastatic prostate cancer (ndhrhsmPCa). There is a significant group of patients unable to have docetaxel and are thus currently being potentially under-treated. NICE recognised that there was an unmet need for an alternative drug that could be used in place of docetaxel.

Much discussion was given to the inability to accurately identify this group and the NICE Committee decided that all men presenting with ndhrhsmPCa should be treated as one homogenous group. This decision has effectively reinforced and will prolong the presence of this un-met need.

As part of the appraisal process a public committee slide was presented outlining criteria enabling clinicians to state why they would be prescribing abiraterone for particular patients. NHS England had been part of this consenting process. No comment was made concerning this in the Final Appraisal Document (FAD) giving details of the NICE Committee decision.

The decision by NICE to treat all men as one group has now effectively removed from clinicians the ability to treat their patients as individuals and prescribe as they feel appropriate on clinical grounds. This could be interpreted as a curtailment of their clinical freedom.

Age and patient selection:

Prostate Cancer UK have obtained data from Public Health England which show the usage of docetaxel in ndhrhsmPCa. This shows usage is very heavily biased to men under the age of 70. For many reasons, the ability to tolerate chemotherapy reduces as age progresses and therefore these older men are less likely to receive the best standard of care with combination therapy: i.e. ADT with docetaxel. Such men often tolerate abiraterone better than chemotherapy. It could be argued that the NICE decision now discriminates against these men purely because of their age and the changes in health that accompanies it. Just because a man is getting older should not mean that he is denied potentially beneficial treatment – and one that is kinder and an effective alternative.

The 'Postcode Lottery':

In December 2019 abiraterone was discussed by the Scottish Medicines Commission for use in exactly the same clinical scenario as this current NICE appraisal. Similar data and arguments were put forward. In January 2020 the SMC gave their decision to approve the use of abiraterone for all men with ndhrhsmPCa. There is now a divide in the availability of treatment – purely being decided by where a man lives. It has to be accepted that, with devolution of government, such inequalities will exist – not only in disease management but in many other areas. It also has to be recognised that a decision by one body in one area does not automatically mean it will be ratified by a similar body elsewhere. However, patients will be very confused why diametrically opposed decisions can result from examination of the same facts. It is a tragedy that men in England and Wales will still not be able to benefit from abiraterone on the NHS at the time when they are first diagnosed.

Cost effectiveness:

It is not the remit of a patient-centred body such as Tackle to be able to pass comment on this unless made by experts in the field. However, it cannot go un-noticed that a pricing agreement was reached with NHS Scotland but seemingly not possible with NHS England. It is also relevant to comment that abiraterone is already a generic (and therefore much cheaper) product in USA. Abiraterone will become generic in UK in the next 12 months or so. This will then have a

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considerable further impact on the calculation of cost-effectiveness. Whether this resultant change in pricing will then have any influence on any future NICE guidance is yet to be seen.

Earlier use of abiraterone in the treatment pathway:

NICE have stated that if abiraterone is used earlier in the treatment pathway then it will not be available to the patient for use in the more advanced stages of the disease. This could also imply that enzalutamide could not be used instead of abiraterone at that later stage in the disease either. Historically both drugs were approved by NHS England for use in advanced PCa. However, only one of the two could be given in the treatment pathway. The reasoning of this was that there was no evidence directly comparing the two drugs that showed one was superior to the other when used in this context.

Abiraterone and enzalutamide have different modes of action. It could be logically argued that if abiraterone was initially helpful in controlling the disease when used early, but then disease progression occurred, then the use of a drug with a different mode of action (e.g. enzalutamide) may well have additional benefit for the patient when used later. Sadly, as yet there is no current evidence to support the sequential use of these drugs.

However, the old decision concerning funding of these drugs remains in place and would currently negate such a theoretical argument. Certainly when the original funding of both drugs was agreed cost was a huge issue. Once both drugs become generic, could there be the possibility of a change in this decision? The possibility of the future use of generic drugs does not seem to have been considered by NICE. Some chemo-ineligible patients would undoubtedly take a very pragmatic attitude to this:

"I would certainly choose something (i.e. abiraterone) to be used now rather than nothing at all. If it restricts my treatment choices later on, then so be it. I'm willing to take that chance. Who knows, something else might be available by then. I don't have much of a long-term future to look at – I am far more concerned with what happens to me now....."

The role of future drugs in 'chemo-ineligible' patients:

The recognised un-met need for chemo-ineligible patients still remains. Approval for other drugs to be used in ndhrhsmPCa is being sought and going through the NICE appraisal process. Obviously each application will be considered separately. Each application will have different data submitted. Costings for each drug will be different.

The great fear is that if NICE continue to treat all men with ndhrhsmPCa as a single homogenous group and are unable to consider chemo-ineligible patients as a separate entity then these further drug applications are highly likely to fail for the same reason that abiraterone has failed.

There could be a distinct possibility that the un-met need of chemo-ineligible patients will remain an un-met need for a considerable period of time.

The continuation of multi-modal therapy:

The concept of using multiple drugs as initial therapy for other cancers is well recognised by men with prostate cancer. The older method of using only one treatment modality and waiting until that failed before adding or substituting another is rapidly becoming outdated. The concept of early multi-modal therapy for prostate cancer is still relatively new. PCa is, in some respects, way behind other cancers.

As a patient-focussed group, Tackle is committed to ensuring that the most appropriate treatments are always available for patients. It is essential for those men and their families that they achieve the optimal balance between quality and quantity of life. There are still many areas where improvement can still be made.

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