

Focused Ultrasound Case Study

Prostate Cancer



This year, we're taking a closer look at several aspects of focused ultrasound, FUS, as it compares to current standards of care, in the treatment for prostate cancer. Included in the analysis: disease control, side effects, economics and a brief analysis of the market opportunity.

Disease control

Two recent studies were used to compare the effectiveness of FUS to the current standards of care for the treatment of prostate cancer:

- A UK Multicenter, prospective study of focused ultrasound that included 625 patients.¹
- The ProtecT trial, in which 553 men were treated with **radical prostatectomy** and 545 with external beam radiation therapy, or referred to simply as **radiotherapy**.²

Despite an advanced cancer progression for patients enrolled in the UK study,³ FUS was found to be equivalent to

prostatectomy and radiotherapy, with a 100 percent rate of five-year prostate cancer-specific survival. Beyond this, there are other metrics that can be used to evaluate the effectiveness of prostate cancer treatment.

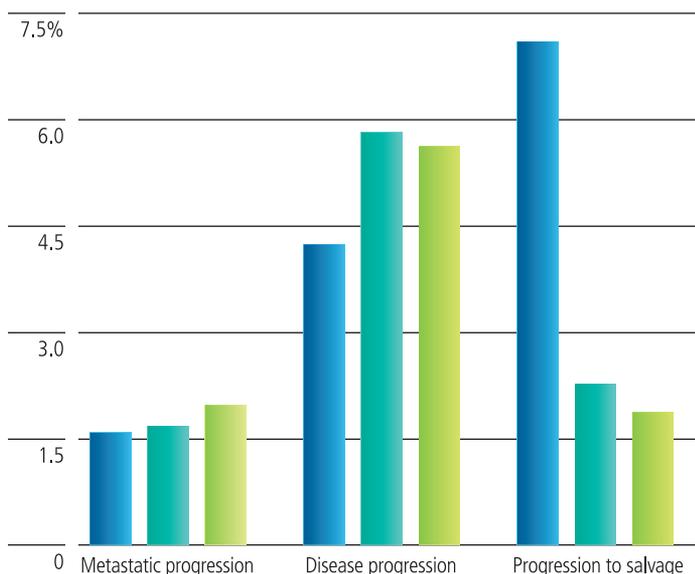
FUS led to better outcomes than prostatectomy and radiotherapy for both metastatic progression and disease progression. Where FUS did not perform as well was in the progression to salvage therapy, which is the need for follow-up treatment after disease recurrence. This outcome is not unexpected given that, prior to treatment, a reasonable proportion of patients in the UK study were diagnosed with cancer that had spread outside of their prostate (Stage T3: 14 percent), while none of the patients in the ProtecT trial had this issue.³

Side effects and their impacts

Four key studies were used to compare the side-effect profile of treatment with FUS to that using prostatectomy or radiotherapy, with a total of 7,675 patients.^{1, 4, 5, 6}

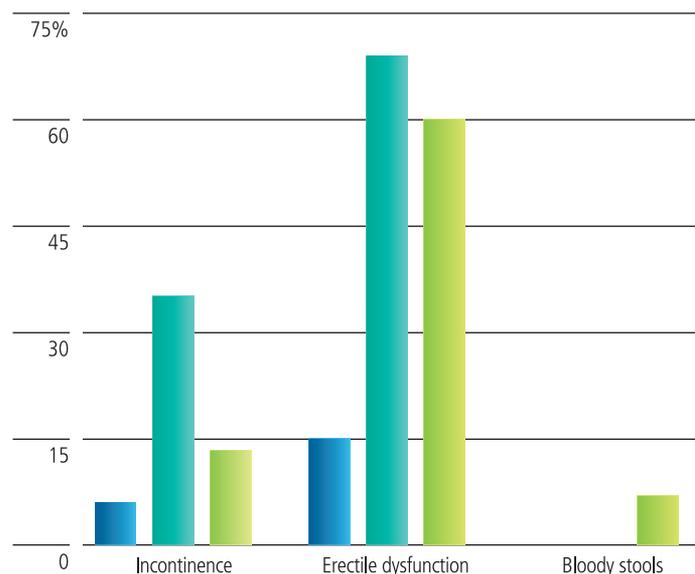
Disease Progression

■ Focused ultrasound ■ Prostatectomy ■ Radiotherapy



Side Effects

■ Focused ultrasound ■ Prostatectomy ■ Radiotherapy



By comparing reported side effects from each treatment, FUS was shown to have a substantially lower overall side-effect profile as compared to prostatectomy and radiotherapy. In addition, the recommended time for returning to activities of daily living following FUS treatment—including driving, vigorous activity, and resuming work functions—is two days. In contrast, a return to all normal daily activities was shown to take up to 10 weeks following prostatectomy.^{7,8} In another study, surgery or radiotherapy for the treatment of prostate cancer led to 46 and 44 days of sick leave, respectively.⁹

Economics¹⁰

The economics of a procedure can be evaluated based on costs, reimbursement rates, and reimbursement net of costs.

The overall cost of FUS to the facility (primary facility costs plus the cost of the device) and to the physician are

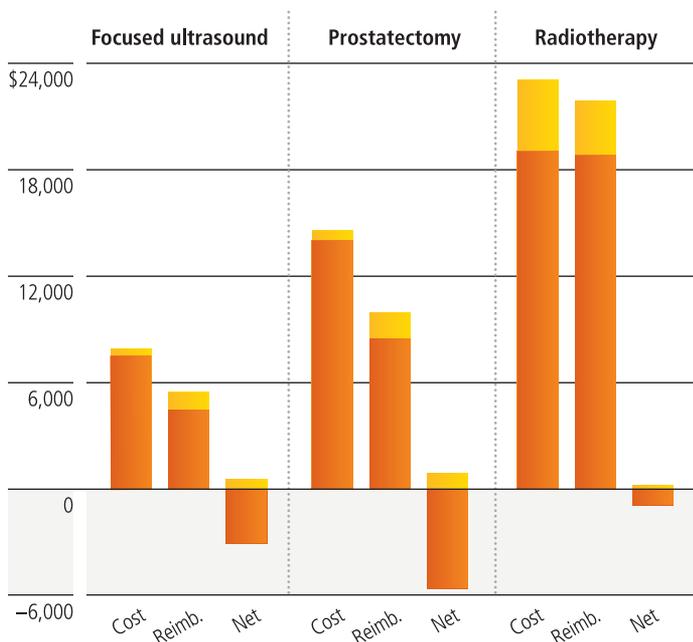
substantially lower than that for competing technologies. However, because of differences in Medicare payment levels, net physician reimbursement is positive only for those treating with FUS or prostatectomy. In contrast, net facility reimbursement is only positive when radiotherapy is used as the treatment method.

Economics also can be gauged by the overall cost to society. These costs include: payment for the primary procedure, follow up-office visits (including testing and follow-up procedures), costs associated with side effects, and wages lost due to missed time from work.

Based on the overall economic impact to society, FUS is substantially more cost-effective than either prostatectomy or radiotherapy. This is largely the result of substantially less time lost from work, reduced costs of treating side effects, and a significantly lower payment for the primary procedure.

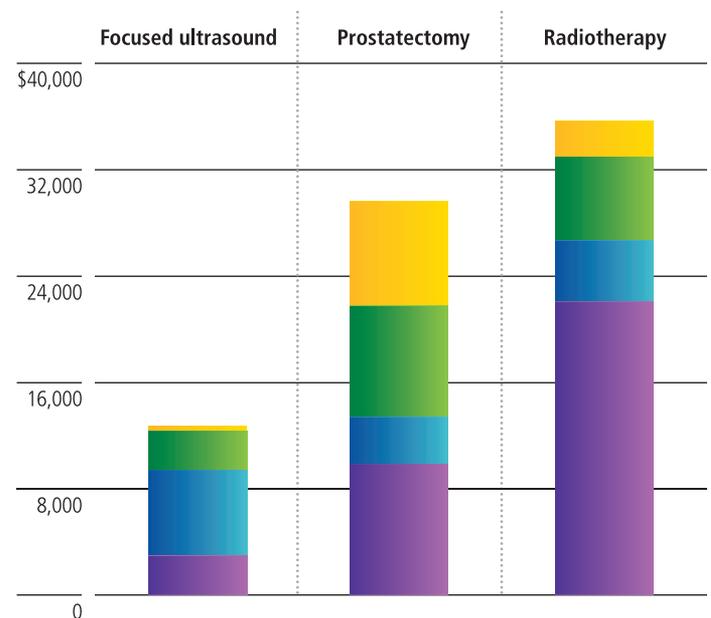
Economics

Facility Physician



Overall Cost to Society

Initial procedure Follow-up Side effect Lost wages



Market opportunity

In 2020, there were 1,414,259 cases of prostate cancer globally.¹¹ In the US, the annual number of cases is thought to range from 170,000¹² to 240,000^{9, 13}. To be conservative in our market estimates, we used the lower of these values.

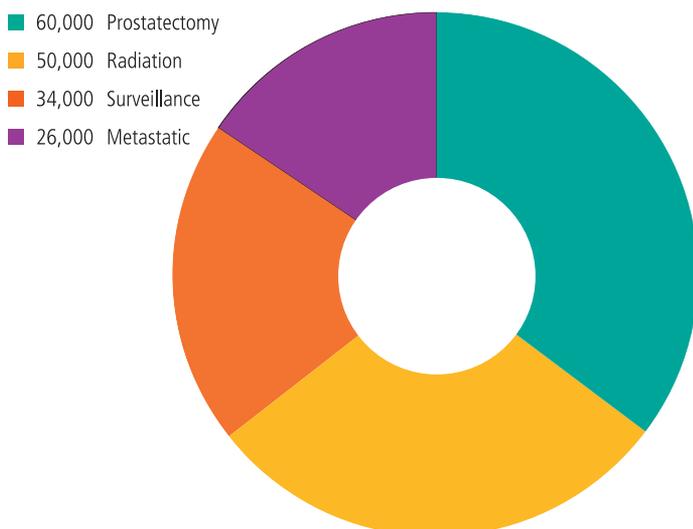
Based on conversations with urologists as well as publicly available data,^{14, 10, 15} we've parsed the overall US market into the estimated segments shown in the pie chart below. Despite there being 170,000 annual prostate cancer cases in the US, data in the accompanying table demonstrates that the number of patients for which FUS treatment is clinically recommended, the total US market, is closer to 148,000. Not all of these patients will have access to FUS as a treatment option; patients cannot get access to FUS treatment if their medical center does not offer it. To calculate the US FUS market, we factored the total US market by the ratio of FUS treatment sites to all prostate cancer sites. Our records

indicate that, in 2020, there were 126 FUS prostate cancer sites in the US, whereas there were approximately 2,000 total US medical centers treating prostate cancer. Accordingly, the US FUS market is approximately six percent of the total US market.

In all, we estimate that the US market for FUS is about 9,200 patients annually. If this value is extrapolated to all global prostate cancer patients, we project a global FUS market of over 76,000 prostate cancer patients.

Data from our annual survey of device manufacturers indicate that 6,529 global FUS treatments for prostate cancer took place in 2019 (to exclude the potential impact of COVID-related restriction on 2020 data). This suggests that the use of FUS for the treatment of prostate cancer has yet to achieve its full market potential.

Market Opportunity



	Total US market	US FUS market
Primary therapy		
Low to intermediate risk*	94,000	5,849
Surveillance	34,000	2,116
Total primary	128,000	7,964
Salvage therapy		
	20,000	1,244
Total	148,000	9,208

*Gleason 7 or high-volume Gleason 6

Conclusions

Focused Ultrasound has been used to treat prostate cancer for almost two decades, but has not gained the expected market traction in light of the overall advantages that FUS treatment provides to patients.

Overall, FUS-based prostate cancer treatment offers patients a means of disease control that is mostly equivalent to prostatectomy and radiotherapy, yet with a side-effect profile that is more attractive than that of the current standards of care. FUS also enables a quicker return to activities of daily living, with reduced costs to physicians, facilities, and society as a whole. The only real downside to the use of FUS is the low reimbursement rate for treatment facilities.

Since the treatment facilities—not physicians—are the ultimate decision-makers of device purchases, it is incumbent on the entire focused ultrasound field to ensure that reimbursement rates are improved, to the point that the economics of FUS become more advantageous.

Endnotes

- 1 <http://dx.doi.org/10.1016/j.eururo.2018.06.006>
- 2 <https://www.nejm.org/doi/full/10.1056/nejmoa1606220>
- 3 Compared to the ProtecT trial, the average patient in the UK Multicenter study had a higher T Stage and Gleason Score, as well as higher PSA levels. As such, we would expect a poorer prognosis for patients in the UK Multicenter than we would for those in the ProtecT trial.
- 4 <https://doi.org/10.1016/j.euo.2018.04.012>
- 5 <https://doi.org/10.1016/j.juro.2018.02.1755> 4S, Supplement: e739
- 6 <https://doi.org/10.1016/j.eururo.2018.02.012>
- 7 <https://doi.org/10.1001/jamasurg.2013.131>
- 8 <https://doi.org/10.1016/j.jval.2015.12.019>
- 9 <https://doi.org/10.1136/bmjopen-2019-032914>
- 10 Data in this section are based on internal calculations
- 11 <https://gco.iarc.fr/tomorrow/en/dataviz/tables?cancers=27>
- 12 <https://www.urologytimes.com/view/cdc-warns-incidence-of-metastatic-prostate-cancer-on-the-rise>
- 13 <https://seer.cancer.gov/statfacts/html/prost.html>
- 14 <https://www.pcf.org/about-prostate-cancer/prostate-cancer-treatment/active-surveillance/>
- 15 <https://doi.org/10.1038/s41585-020-0287-y>

2021 State of the Field

This case study appears in the *2021 State of the Field Report* which is available on the Foundation's website.

The report documents the progress that is only possible through the hard work, time, and resources of everyone in our community.

New this year: an in-depth analysis of all research areas; the cumulative number of mechanisms of action by indication and stage of research; and a detailed look at industry trends, regulatory approvals, and investments in the field.

