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Original Article

Refining partial gland ablation for localised prostate cancer: the FALCON project

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Objectives

To provide a contemporary statement on focal therapy (FT) for localised prostate cancer (PCa) from an international and diverse group of physicians treating localised PCa, with the aim of overcoming the limitations of previous consensus statements, which were restricted to early adopters, and to offer direction regarding the various aspects of FT application that are currently not well defined.

Materials and Methods

The FocAL therapy CONsensus (FALCON) project began with a 154-item online survey, developed following a steering committee discussion and literature search. Invitations to participate were extended to a large, diverse group of professionals experienced in PCa management. From 2022 to 2023, a Delphi consensus study consisting of three online rounds was conducted using the Modified Delphi method. A 1–9 Likert scale was used for the survey, which was followed by an in-person expert meeting. The threshold for achieving consensus was set at 70% agreement/disagreement. Six main aspects of FT were covered: (i) patient selection; (ii) energy source selection; (iii) treatment approach; (iv) treatment evaluation and follow-up; (v) treatment cost and accessibility; and (vi) future perspectives.

Results

Of 246 initial participants, 148 (60%) completed all three rounds. Based on participant feedback, 27 new statements were added in the second round, and 33 questions related to personal expertise, for which consensus was not necessary, were

excluded. After the third and final round, consensus had not been reached for 69 items. These items were discussed at the in-person meeting, resulting in a consensus of 57 additional items. Consensus was finally not reached on 12 items. Given the volume of data, the voting outcomes are summarised in this article, with a detailed breakdown presented in the form of figures and tables.

Conclusions

The FALCON project delivered a significant consensus on the approach to FT for localised PCa. Additionally, it highlighted gaps in our knowledge that may provide guidance for future research.

Keywords

prostate cancer, ablation techniques, Delphi study, consensus, patient selection, energy source selection, treatment evaluation

Introduction

Worldwide in 2020, over 1.4 million men were diagnosed with prostate cancer (PCa) [1], with approximately 80% diagnosed at local or regional stage. The large number of affected men, combined with the adverse effects of standard treatments such as radical prostatectomy and radiation therapy on sexual, urinary and bowel function [2], makes exploring alternative treatments imperative.

Initially, active surveillance emerged as a means of delaying or avoiding treatment. However, it is important to note that this approach is not recommended for all patients [3]. Focal therapy (FT) was developed to address this gap, with the objective of improving functional outcomes for men with localised PCa who are not eligible for active surveillance without compromising oncological outcomes. Currently, data support the functional benefits of FT, including minimal impact on continence and erectile function [4], but evidence from long-term oncological outcomes from clinical trials and well-designed registries remains scarce.

Focal therapy evolved hand in hand with technology. Nowadays, the cornerstone of FT is the deployment of MRI to precisely identify the location of the index lesion and to guide target biopsies and treatment for the lesion considered to be responsible for spreading and driving PCa toward a lethal metastatic state [5,6]. In the future, lesion localisation and staging might be further refined with novel technologies such as micro-ultrasonography, prostate-specific membrane antigen positron emission tomography (PSMA-PET), epigenetics, and artificial intelligence, which may refine MRI interpretation and further advancements in the field [7–9]. Regarding treatment planning, lesion targeting can be achieved via cognitive or software-based fusion, with the choice of energy source and application route (transperineal, transrectal, transurethral) being dependent on lesion characteristics [10,11].

Heterogeneity in the field of FT stemming from this rapid evolution of technologies presents a challenge as it leads to changes in medical practice before outcomes have been thoroughly evaluated. Variations in patient selection, treatment, and follow-up protocols impede the evaluation of comparative oncological outcomes. Furthermore, there is limited guidance on controversial issues in the field of FT, including patient selection, type of energy to be used, and timing and method of post-treatment biopsies [12]. Uncertainty on such topics underscores the need for an updated consensus while, in parallel, more robust studies addressing these issues are conducted.

Prior FT consensus studies were developed to address the aforementioned issues but these had several limitations; for example, they only included pioneers and early adopters of FT, which may give a biased viewpoint. Furthermore, most studies focused solely on patient selection, treatment, or follow-up rather than addressing a broader range of debated topics about FT. Although these studies were published, results were not necessarily considered in real-world clinical practice. A large and diverse pool of participants is needed to improve the quality of consensus studies and promote the application of their results [12]. The FocAL therapy CONsensus (FALCON) project was therefore created to address the controversial aspects of FT by establishing a broad, international consensus from a large number of physicians with diverse backgrounds, with the ultimate goal of impacting real-world practice.

Materials and Methods

Literature Review

A 154-item English-language questionnaire was developed after a steering committee meeting, which was followed by a non-systematic review of the literature to determine gaps in FT knowledge. The steering committee members are listed in Appendix S1. In November 2022, the PubMed database was searched for articles published in English from October 2012 to October 2022 using the terms ‘focal therapy’ AND ‘prostatic neoplasms’, with a focus on identifying systematic

reviews and previously published Delphi consensus studies. Based on this information, a survey was designed, with the following six sections: (i) patient selection; (ii) energy source selection; (iii) treatment approach; (iv) treatment evaluation and follow-up; (v) treatment cost and accessibility; and (vi) future perspectives.

Participants

Stakeholders, specialised in different domains of PCa care, were invited to participate in the Delphi consensus rounds. Specialties included urologists, medical oncologists, radiologists, radiation oncologists, and pathologists. Participants were recruited via direct mail from steering committee members, with support from the Focal Therapy Society, the *Confederación Americana de Urología* and the *Société Internationale d'Urologie*, who promoted the project on social media. To maintain control, direct access to the survey through social media was not allowed.

Consensus Development

The FALCON project used the modified Delphi method [13,14]. Given the lack of consistency in the Delphi methodology, with slight variabilities among different studies, a protocol was developed to predefine the survey design. This included the sections and statements to be included, the stakeholders involved, strategies for distributing the survey, and the threshold for consensus [15–17]. From December 2022 to October 2023, three rounds of Delphi consensus were conducted using the web-based DelphiManager software (Liverpool, UK) [17]. The survey used a 1–9 Likert scale (1–3 disagree; 4–6 equivocal; 7–9 agree) with an additional option, 'Unable to rate'. At each subsequent round, the results of the prior round were shared, and participants were reminded of their responses. Participants were allowed to change their responses, share feedback on the statements, and suggest new statements to improve the survey for the next round. The threshold for consensus was set at a minimum of 70% (agreement or disagreement) of the respondents. After the second round, which included all statements from the first round plus those added by the respondents, all statements that reached consensus and those related to personal expertise for which consensus was deemed unnecessary were removed. For the project's final phase, a 4-h in-person meeting was held on 12 October 2023, in Istanbul, Turkey, and included in-person and virtual attendees. This phase included a fourth survey, followed by a discussion to attempt to achieve consensus on items for which consensus was not reached in previous rounds. Items that reached consensus previously were also discussed, and if needed, were modified slightly to improve clarity for future readers.

Results

Literature Review and Survey Development

The literature review yielded 14 systematic reviews and nine Delphi consensus studies on FT (Table S2). Based on the results of this search, the survey was divided into the six sections described above. These domains were further divided into the sub-domains shown in Fig. 1.

Participant Information

Of 246 initial participants, 148 (60%) took part in all three Delphi rounds. Most participants in each of the three rounds were urologists, although radiation oncologists, radiologists, pathologists, and oncologists were also represented (Fig. 2).

Survey Results

A flowchart of the Delphi process is included in Fig. S1. Briefly, the survey started with 154 items. Twenty-seven new statements were added in the second round based on respondent suggestions. Thirty-three statements related to personal expertise were excluded after the second round. The results for these statements are presented in Table S3. Statements for which consensus was reached during the second and third rounds were removed from subsequent rounds. Statements for which consensus was reached after the three online rounds are presented in Tables S4, with consensus reached on 53 statements in Round 2 and 25 statements in Round 3.

After the third and final online round, a consensus was not reached on 69 statements. These statements were included in a fourth survey completed by attendees at the beginning of the in-person meeting. Through this survey, consensus was reached on an additional 50 statements and these were subsequently discussed to validate the results (Tables S5 and S6). During the in-person meeting, nine people participated in person, and five others connected via Zoom for at least 1 h. Following an in-person discussion of the 19 statements on which consensus was not reached in the fourth survey, consensus was reached on seven additional statements. In total, consensus was reached on 135 items after the three Delphi rounds and the in-person meeting.

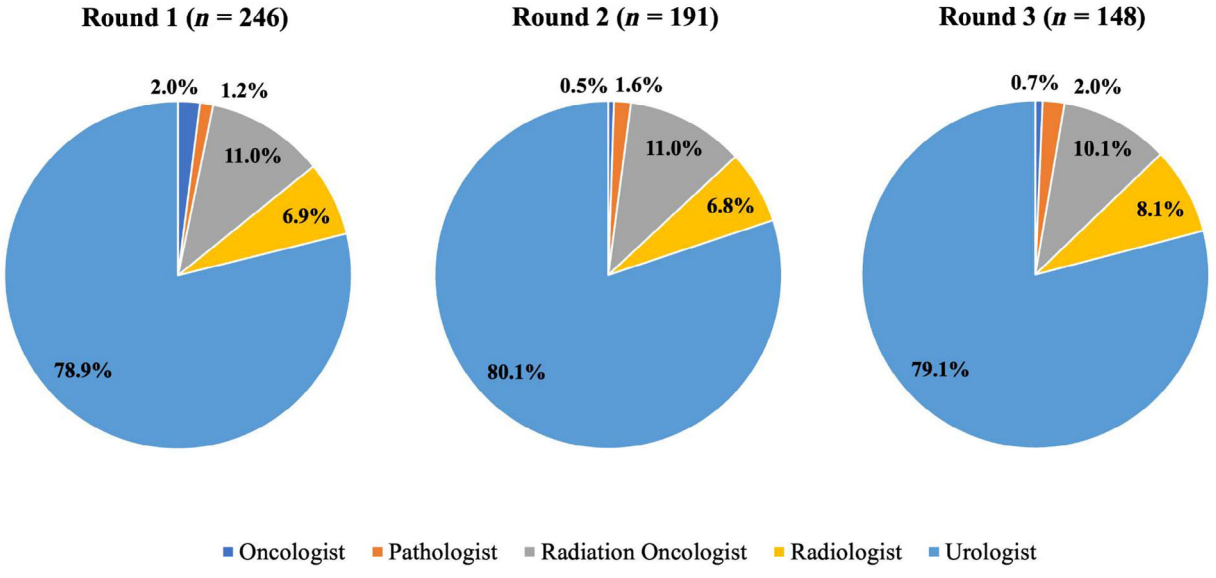
All the statements for which consensus was reached are listed in Table S7.

Patient Selection: Life Expectancy

The consensus was that age should not be a determining factor for FT; instead, life expectancy should be considered,

Fig. 1 Overview of FALCON domains and sub-domains.

Fig. 2 Specialties of participants in the three Delphi rounds.



and treatment should be avoided for patients with a life expectancy of <10 years.

Patient Selection: Sexual Activity and Voiding Symptoms

The ideal candidate for FT would be a sexually active man with mild to moderate voiding issues (whether treated medically or surgically) who seeks to treat his PCa with minimal impact on functional outcomes. However, this would not exclude men with erectile dysfunction or significant voiding symptoms from being suitable candidates for FT.

Patient Selection: Biopsies

According to the consensus, systematic bilateral biopsies combined with targeted biopsies are required prior to FT. Candidates should undergo 3–4 targeted biopsies (MRI in-bore biopsies, MRI/ultrasonography fusion biopsies, or cognitive fusion biopsies) and 10–12 systematic biopsies, with saturation biopsies or transperineal mapping biopsies, as described by Winston Barzell [18], considered unnecessary.

It was agreed that FT should not be offered if MRI is unavailable, is of low quality, or is negative while biopsies are positive. Moreover, there was consensus against the statement: 'FT may be offered even if MRI is unavailable or of low quality, as long as mapping biopsies, as described by Winston Barzell, are performed'. However, no consensus was reached regarding the statement: 'FT should not be offered in cases of negative MRI and positive biopsies, even if mapping biopsies by Winston Barzell are performed' (Statement 25, Table 1).

The presence of positive biopsies outside the MRI-detected lesion would not be an absolute contraindication for FT. FT may still be considered if unexpected out-of-lesion International Society of Urological Pathology (ISUP) grade 1 biopsies are found, regardless of their number, location, or proximity to the target lesion. Unexpected out-of-lesion ISUP grade 2 biopsies may also be acceptable, provided they are close to the target lesion and can be treated simultaneously.

Table 1 Statements for which consensus was not reached.

Domain	Statement number	Statement
Patient selection: Biopsies	12	Prostate cancer diagnosis through transperineal biopsies is mandatory before FT
Patient selection: MRI lesions and positive biopsies' location	21	FT may be offered to patients who cannot undergo MRI if it is replaced by PSMA
	25	FT should not be offered in case of negative MRI and positive biopsies even if mapping biopsy, as described by Winston Barzell, was performed
Patient selection: PSA level	71	Candidates for FT should have a PSA value ≤20 ng/mL regardless of PSA density
Patient selection: Local clinical stage on MRI	77	FT should only be considered if the clinical stage on MRI is ≤T2c
Patient selection: Cribriform and intraductal patterns	86	The presence of cribriform and/or intraductal patterns are contraindications for FT
Treatment approach	108	The treatment of the lesion is insufficient and at least all prostate tissue within a quadrant of the prostate should be treated (quadrant ablation)
Treatment evaluation and follow-up	126	PSA failure after FT is nadir PSA + 2 ng/dL
	129	Follow-up with MRI and PSA is sufficient
	131	Follow-up with PSMA imaging may be superior to MRI
Future perspectives	145	In the next 5 years, patients with oligometastatic disease may be candidates for FT
	146	In the next 5 years, locally advanced disease on MRI will not be always a contraindication for FT

Abbreviations: FT, focal therapy; PSMA, prostate-specific membrane antigen.

Patient Selection: Number of Lesions on MRI

Multifocality on MRI would not contraindicate FT, with treatment reserved for lesions confirmed by anatomopathological findings from biopsies.

Patient Selection: Location of the Target Lesions

In selecting patients for FT, PSMA-PET would not be considered a suitable replacement for MRI. Lesions less than 5 mm from the rectum may be treated with FT, while lesions less than 5 mm from the sphincter should not be treated. However, maintaining a minimum 10-mm distance from the sphincter was not considered mandatory.

All lesions can be treated with FT, provided they can be safely accessed by the chosen energy source. During the final meeting, high-intensity focused ultrasonography and irreversible electroporation were considered safe energy options for lesions close to the rectum, while irreversible electroporation was deemed a safe energy source for lesions near the sphincter. No single energy source was considered to guarantee favourable oncological and functional outcomes for all lesion locations.

Patient Selection: Prostate Volume

According to the consensus, prostate volume is not a limiting factor if the lesion can be safely accessed. The prostate volume threshold varies by energy source and lesion location.

Patient Selection: Tumour Volume

Tumour volume on MRI was considered an important factor when using FT to treat patients with PCa. Tumour volumes >1.5 cm^3 could be treated, and tumour volume ≤50% of the total prostate volume was also deemed suitable for FT. No statements regarding the treatment of larger tumour volumes were included in the consensus.

Patient Selection: PSA Level

Patients' PSA level should be considered an inclusion or exclusion criterion for FT. Candidates may have a PSA level >15 ng/mL/cc, but PSA density should remain below 0.2, as determined during the final face-to-face meeting.

Patient Selection: Local Clinical Stage on MRI

Based on respondent opinions, local staging should be based on MRI rather than rectal examination. There was consensus that FT should not be offered if there is a likelihood of extracapsular extension (ECE) on MRI. While consensus was reached that patients with a clinical stage of ≤T2b on MRI are suitable for treatment, no consensus was reached on setting the threshold at ≤T2c for MRI-detected disease (Statement 77, Table 1).

Patient Selection: Gleason Score

Over 70% of respondents agreed that FT should not be offered to patients with localised ISUP grade 1 PCa if they are eligible for active surveillance, but it may be offered to patients with ISUP grade 2 disease, regardless of the percentage of pattern 4. Based on the final meeting, FT should be offered to patients with ISUP grade 3 PCa, but not to those with localised PCa of ISUP grade >3.

Patient Selection: Cribriform and Intraductal Patterns

There was consensus that FT may be considered in preference to active surveillance for patients with localised ISUP grade 2 PCa (with a percentage of pattern 4 less than 10%) if a cribriform pattern is present. It was also agreed that patients with the *BRCA* gene mutation should not be offered FT, and that the results of tissue genomic tests from biopsies (e.g., Decipher, Prolaris) could influence the decision to offer FT. On the other hand, participants agreed that germline genetic testing and tissue genomic tests from biopsies (e.g., Decipher, Prolaris) should be offered to all patients prior to FT.

Energy Selection

Regarding energy selection, the survey indicated that this should primarily be based on the surgeon's experience, with the preferred energy being the one the practitioner feels most confident using, as well as on the location of the tumour. After the final meeting, it was agreed that high-intensity focused ultrasonography or cryotherapy should be the first energy sources considered, as they are supported by the most data, even though much of the data is retrospective.

Treatment Approach

Only the lesion identified on MRI, along with an appropriate safety margin, should be treated. Different energy modalities should be employed depending on the location of the index lesion. The minimum margin for treating the lesion was agreed to be 5 mm, with consensus against using 10 mm as the minimum margin. Additionally, there was consensus against considering hemiablation as the minimal treatment extension.

Treatment Evaluation and Follow-Up

Based on the survey, patients should be followed for up to 10 years, with PSA testing every 3 months during the first year and then every 6 months thereafter. Early MRI, within a week after treatment, was not highly recommended, and based on the final face-to-face meeting, it should be performed on an annual basis. Regarding biopsies, 10–12 systematic plus 3–4 targeted biopsies should be performed at 12 months post-treatment, and then only if there is clinical suspicion. However, no consensus was reached on the possibility of follow-up using only PSA and MRI (Statement 129, Table 1).

Functional outcomes should be assessed every 3 months for the first year, then annually until stability is achieved. The definition of PSA failure should depend on the ablation template used (lesion-only, quadriablation or hemiablation), with consensus reached that there is no specific PSA failure definition after FT. Dedicated scoring systems for prostate MRI reporting post-FT should be developed and validated in a multicentre setting. Lastly, patients may be offered additional salvage FT following the failure of an initial treatment.

Future Perspectives

Respondents agreed on the importance of PSMA-PET and the combination of systemic treatments and radiotherapy with FT in the future management of PCa treated with FT.

The 12 statements for which no consensus was reached are summarised in Table 1. These were primarily related to patient selection and follow-up. Specifically, there was no agreement on whether to use transperineal or transrectal biopsy approaches when planning FT. Uncertainty also persisted about whether MRI-guided biopsies could be replaced by PSMA-guided or saturation biopsies prior to FT. Additionally, no consensus was reached on clinical staging or PSA thresholds, nor on the significance of intraductal and/or cribriform patterns. In terms of follow-up, disagreement remained regarding the definition of PSA failure, follow-up strategies with or without control biopsies using only MRI and PSA, and the role of PSMA-PET in this setting. Treatment extent also proved controversial, particularly regarding the minimum necessary extension. Looking ahead, respondents were divided on the future role of FT in localised advanced PCa and oligometastatic scenarios.

Discussion

The FALCON project aimed to enhance the current body of literature by recruiting a large and diverse group of participants across multiple countries to address the controversial aspects of FT. During the 10-year time frame of the literature review, at least nine consensus studies on FT were published. Nonetheless, these studies focused on specific aspects of FT rather than taking a comprehensive approach. Additionally, the FALCON project, with 148 participants completing the three Delphi rounds, overcame the limitation of past consensus studies that rarely reached more than 50 participants for the third Delphi round [19–24].

While acknowledging that Delphi techniques are among the lowest levels of evidence for causal inference, it is still a useful methodology in areas where gaps in the literature exist [13]. The FALCON project was developed to establish a contemporary and international consensus on how to manage patients treated with FT from patient selection to follow-up. The goal was to include a wide and varied list of participants with different views on the same topics to reduce the biases that may occur by including only one specialty of physicians or limiting participants to experts in the field.

Some relevant findings are particularly noteworthy and deserve to be highlighted. Regarding patient selection, inclusion criteria for FT are not standardised, with variations in the threshold for PSA level, clinical stage, ISUP grade, number of lesions visible on MRI, and volume and location of index lesion, among others. One of the more controversial aspects of patient selection pertains to ISUP grade. As technology and experience evolve, leading to improved diagnostic and treatment accuracy, more aggressive forms of the disease are increasingly being treated [25]. While ISUP grade 2 PCa is accepted as the best candidate for FT, there is debate about using FT for ISUP grade 3 [24]. The FALCON project determined that FT should be offered to patients with localised ISUP grade 3 PCa and should not be offered to patients with localised ISUP grade >3 PCa. Nevertheless, it should be acknowledged that, although consensus on the role of FT for ISUP grade ≥3 PCa was reached during the final meeting, the topic remained controversial during the online Delphi round, reflecting the lack of strong evidence in this area. Retrospective studies on FT outcomes for ISUP grade 3 PCa report conflicting results, with most studies including 20% or fewer patients with this grade [10,26,27]. For more aggressive disease, the data remain limited, although a few series have included a small subset of these patients [26,27]. Solid oncological outcome data are still lacking, but treatments are already being performed, and more comprehensive data are expected to emerge in the near future.

In addition, there is uncertainty surrounding whether patients with intraductal and cribriform pattern disease should be considered for FT [28]. While there was a lack of consensus on whether or not the presence of cribriform and/or intraductal patterns are contraindications for FT, participants agreed that if cribriform pattern is present, FT should be considered in preference to active surveillance for patients with localised ISUP grade 2 (percentage of pattern 4 <10%) PCa. The lack of consensus on this topic highlights an area where additional research is warranted. Another debated aspect of patient selection involves the consideration of patients with ECE on MRI. Participants agreed that FT should not be offered to patients when a likelihood of ECE is observed on MRI. However, determining what constitutes a 'likelihood of ECE on MRI' may warrant further discussion, as this assessment could be influenced by MRI quality and radiologist interpretation. Furthermore, although the use of nomograms to predict the risk of ECE was not evaluated in the current Delphi consensus, they have demonstrated potential for improving the accuracy of ECE assessment [29]. Finally, there was a consensus that FT should not be offered if MRI is unavailable, negative, or of low quality. However, consensus remains elusive regarding whether PSMA-PET imaging can serve as a substitute in cases where MRI is not feasible for the patient. Additionally, no consensus was reached on Statement 25, which proposed that 'FT should not be offered in cases of negative MRI and positive biopsies, even if mapping biopsy, as described by Winston Barzell, was performed'. These conflicting opinions highlight the urgent need for further research in these areas.

Concerning FT approach, there is debate about the optimal treatment margin when planning FT. One study found that, for tumours up to 12 mm, a 6-mm margin achieved complete ablation of high-grade lesions; the authors concluded that a margin of 5–6 mm is adequate for tumours smaller than 12 mm [30]. Another study found that not all cancers were located within the MRI lesion, but 90% were within 10 mm

of the lesions [31]. FALCON participants agreed that the minimal margin when treating a lesion is 5 mm and disagreed that the minimal margin is 10 mm, meaning that the optimal treatment margin lies within this range. For energy selection, results from FALCON indicated that no energy source can be recommended over another in terms of effectiveness and safety. Instead, energy selection should primarily be based on the location of the tumour (71% agreement) and the operator's experience (77% agreement).

The timing and method for post-treatment monitoring and biopsies are not standardised. Participants in the FALCON project agreed that patients should be monitored for up to 10 years, PSA assessment should be carried out every 3 months for the first year, then every 6 months, and MRI should be performed yearly. The FALCON-proposed yearly MRI and its associated costs may be controversial as this approach has not been shown to be superior to follow-up based on specific triggers (e.g., PSA elevation) or less frequent MRI schedules. Given the lack of robust evidence typical of Delphi studies, this proposal should be approached with caution. Additionally, variations in healthcare systems and participant realities may influence their responses. Similarly, regarding biopsies, 10–12 systematic plus 3–4 target biopsies should be performed at 12 months post-treatment, and thereafter only if there is clinical suspicion, according to FALCON. However, the use of control biopsies varies worldwide, with some groups initially adopting them and discontinuing as they gain experience [32]. This underscores the need for clinical practice to be tailored not only to individual patient cases but also to the specific realities of healthcare centres, including access to high-quality MRI technology, expert interpretation, and experience in FT treatment, beyond the general recommendations of the FALCON project.

Results from the FALCON project should be interpreted with caution because of several limitations. First, a systematic literature review was not conducted prior to developing the survey. Instead, a non-systematic review was performed and relied on previous systematic reviews and consensuses to create the survey. Second, while the goal was to recruit a diverse population of specialists in the field of PCa treatment, almost 80% of participants in the third Delphi round were urologists. Third, with a 154-item initial questionnaire, the survey was time-consuming, and 'respondent fatigue' may have negatively affected the results [33]. Fourth, a consensus was reached on 69 statements through the in-person meeting survey and discussion. It is likely that the views of this smaller group did not represent those of the larger respondent pool, although the goal of this meeting was to achieve consensus through discussion when possible. Lastly, Delphi techniques provide a lower level of evidence generation than clinical trials and well-designed observational studies. Therefore, these recommendations should be applied in conjunction with clinical judgement, and deviations from them are not necessarily detrimental to patient care or local policies. This is particularly important to note, given the need for stronger evidence to transition from guidance to formal guidelines in the future. Additionally, as new data emerge, areas of consensus are likely to evolve, making this a dynamic field that requires continuous evaluation and periodic reassessment to ensure that the guidance stays aligned with the most up-to-date evidence.

Nevertheless, given the insufficiencies in the current literature, a broad international consensus statement appeared warranted. Moreover, registries now appear to be the most viable solution for obtaining robust oncological outcomes, given the high cost and feasibility challenges associated with trials. It is therefore crucial to reduce heterogeneity among patients included in ongoing registries, particularly since practitioners may lack standardised recommendations for performing FT. Without such standardisation, interpreting results can become complex, bringing us back to the initial problem. The FALCON initiative aimed to harmonise FT practices, minimise patient heterogeneity in registries, and enhance the likelihood of generating interpretable outcomes in the future. These ambitious objectives represent the core goal of this extensive consensus effort.

In conclusion, the FALCON project, through an international Delphi consensus methodology, provides comprehensive guidance on FT, covering key areas from patient selection to post-treatment follow-up. Furthermore, the project has highlighted significant gaps in the current evidence base, which could shape future research on FT and contribute to the development of more robust, evidence-based guidelines.

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Disclosure of Interests

The authors disclose the following potential conflicts of interest: Lara Rodriguez-Sanchez is involved in consulting and speaking engagements for AngioDynamics. Additionally, she received speaker fees from EDAP-TMS. Phillip Stricker serves as a consultant for AngioDynamics. Mark Emberton receives research support from the UK National Institute of Heath Research via the UCLH/UCL Biomedical Research Centre. He acts as a consultant/lecturer/proctor for Sonacare Inc., Angiodynamics Inc., Early Health, and Albermale Medical. Bernardino Miñana Lopez declares consulting fees from

Janssen, Astellas, AstraZeneca, Sanofi, Merck, Amgen, Bayer, Werfen, and AngioDynamics. Additionally, he discloses being a proctor for irreversible electroporation (Nanoknife), holmium laser enucleation of the prostate, and prostate robotic surgery, and receives compensation for training other surgeons in these procedures. Jose Luis Dominguez-Escrig declares participation in Clinical Trials from IPSEN Pharma, Janssen, Arquer Diagnostics, Combat BRS, Presurgy, Physion, STORZ, and Angiodynamics. Additionally, he declares consulting fees from Angiodynamics and is currently proctor for irreversible electroporation (NanoKnife). Fernando Bianco serves as a scientific advisor for Angiodynamics. Additionally, he is an investigator for Clinical Laserthermia Systems, SE, and ELESTA SpA, but has never received compensation directly or indirectly from these companies. Furthermore, he is an investigator for Janssen Pharmaceuticals and Merck but has not received any payment from them, nor from any company that he owns. He also holds a shareholder and leadership position in Focalyx. Georg Salomon declares that he has received honoraria, specifically lecture fees, from EDAP. Alberto Bossi has received grants and research support from Janssen, Ipsen, and Sanofi, and has also received honoraria from Accord, Astellas, Elekta Brachytherapy, Ipsen, and Recordati. He is on advisory boards for Accord, Astellas, and Elekta Brachytherapy. Robert Reiter is engaged in consulting and speaking arrangements with Janssen, Lantheus, Bayer, Pfizer, and Astellas. Luca Lunelli provides consulting and speaking services for AngioDynamics. George R. Schade serves as a consultant for EDAP Technomed, Inc. Additionally, he acts as an advisor for Immunity Bio. He also has intellectual property licensed to Petal Surgical. Furthermore, he declares research funding, which includes grants from the National Institutes of Health under grant numbers R01DK119310 and R01CA258581, as well as support from the American Cancer Society under grant number RSG2117101. Veeru Kasivisvanathan received speaker fees for lectures on PCa from the European Association of Urology, Singapore Urology Association, and Clinical Comms Group. Thomas J. Polascik is involved in studies supported by Janssen Bladder Cancer, Myovant Sciences, Prostatype Genomics, Merck, Astellas mCSPC and Astellas mHSPC. Ardeshir R. Rastinehad declares consultant and research support for Philips Healthcare. Rafael Sanchez-Salas declares serving as a Speaker and Consultant for Abbvie Canada, EDAP-TMS, ExactImaging, and Angiodynamics, also noting a spousal relationship with regard to the Angiodynamics involvement. Additionally, he declares serving as a speaker for Janssen Canada, Tolmar Canada, and TerSera Canada. Xavier Cathelineau, Theo M. de Reijke, Anna Lanz, Anita Mitra, Aiman Haider, Eva Compérat, Pilar Laguna, Gaelle Fiard, Peter Ka-Fung Chiu, Pter Macek, Jean J. M. C. H. Rosette and Alejandro Rodriguez have no financial interests or connections, direct or indirect, or other situations that might raise the question of bias in the work reported or the conclusions, implications, or opinions stated, including pertinent commercial or other sources of funding for themselves.

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Abbreviations: ECE, extracapsular extension; FALCON, FocAL therapy CONsensus; FT, focal therapy; ISUP, International Society of Urological Pathology; PCa, prostate cancer; PSMA-PET, prostate-specific membrane antigen positron emission tomography.

Supporting Information

Additional Supporting Information may be found in the online version of this article:

Appendix S1. FALCON group steering committee members and collaborators.

Fig. S1. Flowchart illustrating the development process of the FALCON Delphi consensus.

Table S1. Systematic reviews on focal therapy published from October 2012 to October 2022.

Table S2. Delphi consensuses on focal therapy published from October 2012 to October 2022.

Table S3. Statements pertaining to personal expertise excluded after round 2.

Table S4. Statements reaching consensus during the three Delphi rounds.

Table S5. Statements reaching consensus during the in-person meeting survey.

Table S6. Statements reaching consensus during the in-person meeting after discussion.

Table S7. Final consensus statements from FALCON.