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Establishing consensus recommendations for metastatic hormone-sensitive prostate cancer in South Korea: A modified Delphi study

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Purpose: Consensus is lacking among South Korean urologists on the appropriate treatment of metastatic hormone-sensitive prostate cancer (mHSPC). A modified, Delphi-based consensus on managing mHSPC patients was developed to support clinical decision-making.

Materials and Methods: Thirty-six questions on mHSPC treatment were developed by an expert committee (five urologists). Nine questions required achievement of consensus (key questions). Twenty-three urologists participated in two rounds of a Delphi survey. Consensus was defined as ≥75% agreement among panelists, with ≥90% agreement representing strong consensus.

Results: Eighteen questions (50.0%) reached strong consensus, 15 (41.7%) reached consensus, and three (8.3%) reached no consensus. Eight key questions (88.9%) reached strong consensus and one (11.1%) reached consensus. Consensus was reached on recommending androgen-deprivation therapy (ADT) intensification, irrespective of disease volume or type, with an androgen receptor pathway inhibitor (ARPI) as the preferred option. Not using docetaxel alone with ADT when an ARPI is available for treatment intensification was recommended (strong consensus). For high-volume mHSPC patients with a pathogenic, speckle-type poxvirus and zinc finger protein mutation, ADT+ARPI was recommended over triplet therapy (strong consensus). Panelists recommended regular imaging every 6–12 months if no ARPI reimbursement restrictions exist, but a 3-month interval (per current reimburse-

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ment guidelines) otherwise. ADT+ARPI was the most recommended systemic treatment (strong consensus).
Conclusions: This Delphi consensus established local consensus on controversial areas of mHSPC management. The findings offer meaningful perspectives that may help shape future treatment strategies and encourage thoughtful reconsideration of reimbursement criteria to align evidence and clinical practice in South Korea.

Keywords: Consensus development; Evidence-based practice; Prostate cancer

INTRODUCTION

Prostate cancer is the second most commonly diagnosed cancer among men worldwide [1] and the fourth most commonly diagnosed cancer among men in South Korea [2]. Approximately 10% of prostate cancer cases in Korea are initially diagnosed as at the distant metastatic stage [2], compared to approximately 8% worldwide [3], and the incidence rate of metastatic prostate cancer has increased significantly in the past decade [4].

Metastatic hormone-sensitive prostate cancer (mHSPC, also known as metastatic castration-sensitive prostate cancer [mCSPC]), is a cancer that has spread beyond the prostate to other parts of the body but responds to hormone therapy [5]. Androgen-deprivation therapy (ADT) has historically been recommended as the primary therapeutic approach for mHSPC [6,7]. However, despite often initially responding positively to ADT, mHSPC will often progress to a more aggressive subtype within 2–3 years [8].

Management of mHSPC has evolved with the introduction of treatment intensification (TI) using chemotherapeutic agents (e.g., docetaxel) or androgen receptor pathway inhibitors (ARPIs) along with ADT. There is compelling evidence for TI (ADT+ARPI) from landmark trials showing increased overall survival [9,10], radiographic progression-free survival [10,11], and time to progression of prostate-specific antigen (PSA) [11]. This has led to the recommendation of TI by global prostate cancer treatment guidelines [12-14]. However, despite these recommendations, ADT monotherapy remains a widely used regimen [15,16]. Moreover, there is a need for treatment recommendations based on expert opinions, which should incorporate current and emerging clinical evidence, guidelines, and logistic and economic factors [17]. Therefore, an up-to-date written consensus on treatment recommendations for mHSPC patients in South Korea will help healthcare providers provide treatment as per guideline recommendations.

In addition to TI, numerous clinical questions remain controversial in mHSPC management in South Korea, including topics such as management of: (1) candidates for triplet therapy; (2) frail patients; (3) genomic profiling; (4) domestic monitoring methods; and (5) oligometastatic mHSPC patients.

Given South Korea's distinctive healthcare environment, the primary objective of the current study was to establish expert consensus recommendations on managing mHSPC patients in South Korea (using a modified Delphi-based consensus), and to provide clinicians with comprehensive, evidence-based recommendations to support clinical decision-making.

MATERIALS AND METHODS

1. Ethics statement

The study was conducted in accordance with the protocol, ICH (International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use) guidelines, applicable regulations and guidelines governing clinical study conduct, and the ethical principles that have their origin in the Declaration of Helsinki.

2. Study design and setting

This was a cross-sectional, non-interventional qualitative research study to develop robust recommendations for disease management in mHSPC patients via a modified Delphi approach. The Delphi technique involves gathering expert opinions to reach an informed group consensus on complex problems through a systematic and iterative process [18]. A combination of Delphi and nominal group techniques was used to evaluate group agreement. This modified Delphi approach prioritizes an iterative-yet-streamlined, round-based process to elicit balanced feedback from panelists on which formal consensus analysis methods can be implemented [19-21].

3. Survey development

Meetings with an expert committee of five urologists selected from core members of the current or recent board of directors of the Korean Urological Oncology Society were organized to conduct a comprehensive review of existing evidence and to develop survey forms for the modified Delphi panel. During the meetings, experts evaluated the adoptability of questions regarding mHSPC management used at the Advanced Prostate Cancer Consensus Conference (APCCC) 2022 [17]. Binary questions were used to determine whether each question should be adopted. They also identified additional questions for South Korea-specific mHSPC management. The expert committee's input and decisions were documented in meeting minutes.

4. Modified Delphi panel

Following the expert committee meetings, a structured modified Delphi panel took place to prioritize a set of recommendations for mHSPC management. Variables collected included panelist demographics (i.e., years of practice experience, number of mHSPC patients treated annually, and region of hospital) and panelist responses (categorial) to questions/statements about treatment plans for mHSPC.

Panelists' characteristics and responses to the questions or statements about treatment plans were collected via web-based surveys. The consensus process included a maximum of three engagement periods (i.e., two survey rounds, and a third round if consensus was not reached on key questions) to minimize panelist fatigue and lower the risk of drop-out. If a survey question reached consensus in the first round, it was not included in the second round. Survey rounds were split into two parts to be completed by panelists within three days (maximum one-day extension available). Survey data were analyzed after each round, and anonymized results from the previous round were shared with panelists prior to the next round to facilitate consensus building.

5. Final recommendation development

Final recommendations and evidence documents were developed with the expert committee after completion of survey collection and analysis. See Fig. 1 for study schematics.

6. Participants

The aim was to include 25 urologists (with an acceptable minimum target of 20) from university hospitals in South Korea (one panelist per hospital). Inclusion criteria included: (1) ≥10 years of practice experience, (2) ≥50 mHSPC patients

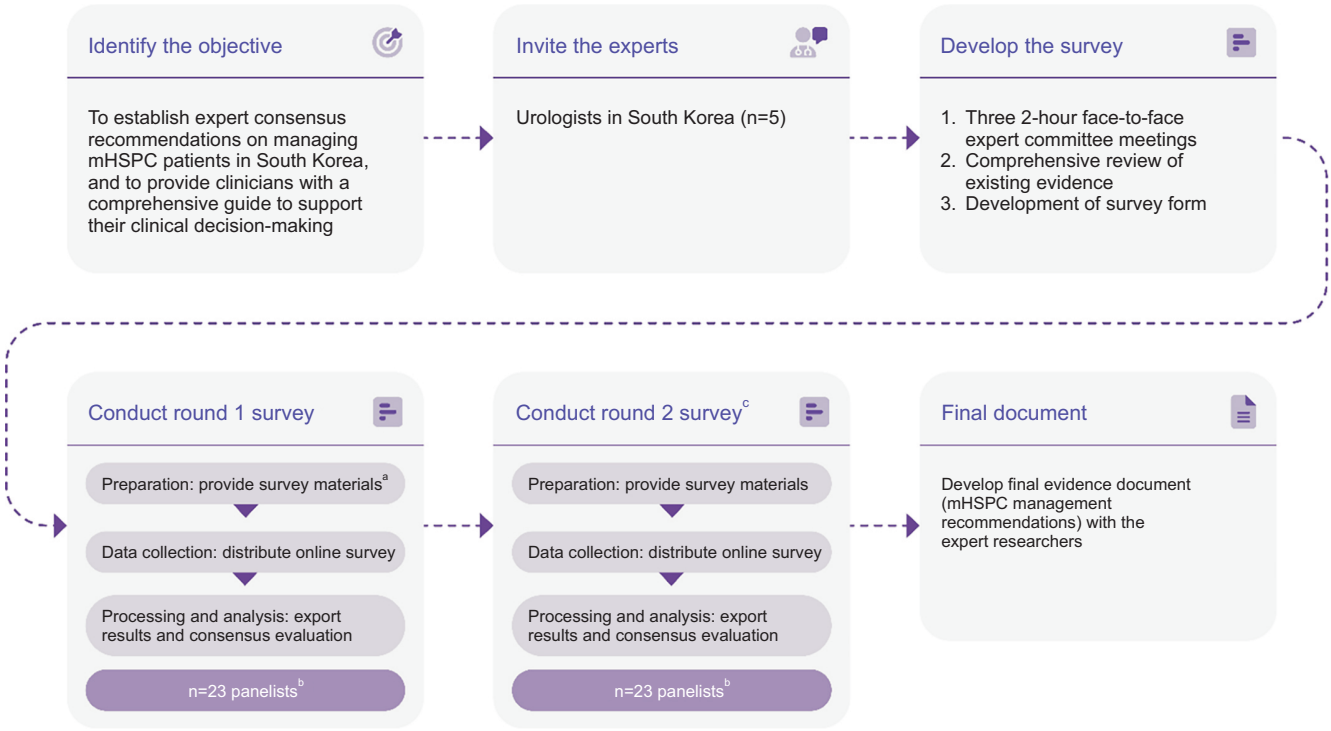

Fig. 1. Study schematic of the modified Delphi panel. mHSPC, metastatic hormone-sensitive prostate cancer; n, sample size. [a]:All panelists were provided with a comprehensive summary of international guidelines and supporting evidence in the treatment of mHSPC as supporting materials before Round 1 survey. [b]:Urologists from university hospitals in South Korea. [c]:All panelists were provided with the results of Round 1 survey before participating in Round 2 survey.

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seen per year, and (3) ≥10 publications in Science Citation Index Expanded journals in the past 5 years. Urologists in private practice were excluded. Participants could withdraw from the study at any time without consequence and without having to provide any justification.

7. Endpoint

The main method of evaluation was consensus among panelists, as defined by ≥75% agreement on each survey question.

8. Statistical analysis

Analyses were descriptive. For continuous variables, mean (with standard deviation [SD]) or median (with minimum and maximum values) were reported. For categorical variables, counts and percentages were reported. For questions and/or statements variables, sample size (N), Cronbach's alpha, and percent agreement among panelists corresponding to threshold criteria for responses which all panelists answered were reported. Cronbach's alpha assessed reliability, with the following criteria applied: 0–0.2 (none), 0.21–0.39 (minimal), 0.40–0.59 (weak), 0.60–0.79 (moderate), 0.80–0.90 (strong), and >0.90 (almost perfect). Percent agreement was defined as the proportion of panelists who chose each response option among respondents who responded to that question. Consensus and strong consensus were defined as the percentage of a response to the specific survey question regarding treatment plan, i.e., percent agreement ≥75% and ≥90%, respectively. Data analyses were performed using Statistical Analysis System (SAS®) version 9.4.1.

9. Missing values

All survey questions were designed to be mandatory using Microsoft Forms. Incomplete surveys with missing responses to any questions could not be submitted. Therefore, there were no missing values in analyses of survey responses.

RESULTS

1. Expert committee meetings/survey development

Thirty-six clinical questions were developed in collaboration with the expert committee. Twenty-eight questions were adopted and modified from the APCC 2022 questionnaire on mHSPC management [17], and eight additional country-

Table 1. Panelist demographics

Variable	Enrolled (n=23)	Completed (n=23)
Years of practice experience		
Mean±SD	22.3±4.9	22.3±4.9
Median	24	24
Min., Max.	14, 33	14, 33
Number of mHSPC patients panelists treat per year		
Mean±SD	227.4±252.7	227.4±252.7
Median	100	100
Min., Max.	50, 1,000	50, 1,000
Number of mHSPC patients panelists treat per year, n (%)		
50–100	12 (52.2)	12 (52.2)
101–300	7 (30.4)	7 (30.4)
301–500	2 (8.7)	2 (8.7)
501–1,000	2 (8.7)	2 (8.7)
Region of hospital, n (%)[a]		
Seoul	10 (43.5)	10 (43.5)
Gyeonggi-do (including Incheon)	4 (17.4)	4 (17.4)
Chungcheong-do (including Daejeon and Sejong)	1 (4.3)	1 (4.3)
Gyeongsang-do (including Daegu, Busan, and Ulsan)	5 (21.7)	5 (21.7)
Jeolla-do (including Gwangju)	2 (8.7)	2 (8.7)
Gangwon-do	1 (4.3)	1 (4.3)
Jeju Island	0 (0.0)	0 (0.0)

SD, standard deviation; Min., minimum; Max., maximum; mHSPC, metastatic hormone-sensitive prostate cancer.
[a]:Percentages add up to 99.9 due to rounding.

specific questions were formulated. Nine of the 36 questions were pre-determined as key questions to target achievement of panelists' consensus. Questions were grouped into recommendations for management of: mHSPC in general (n=6), synchronous and metachronous mHSPC (n=12), frail patients (n=1), genomic profiling in mHSPC (n=4), mHSPC monitoring (n=3), and oligometastatic mHSPC (n=10).

2. Participants

Twenty-three panelists participated in the modified Delphi panel surveys. All panelists completed the Delphi process. The mean (±SD) years of practice experience was 22.3±4.9. The mean (±SD) number of patients treated by the panelists per year was 227.4±252.7. Ten panelists (43.5%) were recruited from university hospitals in Seoul; the remaining were recruited from other regions in South Korea (n=13; 56.5%). See Table 1 for demographic characteristics of panelists.

3. Modified Delphi panel survey

After two rounds of the modified Delphi survey, consensus was reached on all questions except for three under the topic concerning oligometastatic mHSPC. Consensus was reached on all nine pre-determined key questions (Table 2).

1) General mHSPC management

Consensus was reached during the first survey round for all six questions (Table 3).

Panelists endorsed the combination of ADT with additional systemic therapy for mHSPC patients across various conditions and recommended ARPI as a general systemic therapy.

2) Synchronous and metachronous mHSPC management

Consensus was reached on two of 12 questions (one was a key question) during the first survey round and on the remaining ten questions in the second survey round (Table 4).

All panelists recommended triplet therapy only in high-volume synchronous and metachronous mHSPC patients fit to receive chemotherapy. Most panelists (91.3%) recommended ARPI as the sole additional therapy to ADT for synchronous high-volume mHSPC in the current drug approval and reimbursement environment; however, use of docetaxel+ARPI in addition to ADT was endorsed instead

Table 2. Consensus results

Consensus results	Questions
Overall questions (36 total)	
Strong consensus (≥90% agreement)	18 (50.0)
Consensus (≥75% agreement)	15 (41.7)
Non-consensus (<75% agreement)	3 (8.3)
Target (key) questions (9 total)	
Strong consensus	8 (88.9)
What is your general treatment recommendation for the majority of patients with mHSPC? What is your general treatment recommendation for the majority of patients with synchronous high-volume (on conventional imaging or unequivocal on NGI) mHSPC? What is your general treatment recommendation for the majority of patients with metachronous high-volume (on conventional imaging or unequivocal on NGI) mHSPC? What is your general systemic treatment recommendation in addition to ADT for the majority of mHSPC patients? In patients with low-volume mHSPC, do you recommend the addition of docetaxel alone to ADT (assuming that ARPI or triplet systemic therapy is available)? In patients with high-volume mHSPC, do you recommend the addition of docetaxel alone to ADT (assuming that ARPI or triplet systemic therapy is available)? If you recommend systemic therapy for the majority of patients with low-volume/oligometastatic synchronous mHSPC and PSMA PET-positive retroperitoneal lymph nodes (e.g., 1–3 lesions), what is your treatment recommendation? If you recommend systemic therapy in the majority of patients with low-volume/oligometastatic metachronous mHSPC (e.g., 3 bone lesions on NGI), what is your treatment recommendation?	
Consensus	1 (11.1)
What is your general treatment recommendation for the majority of patients with synchronous low-volume (on conventional imaging or unequivocal on NGI) mHSPC?	
Non-consensus	0 (0.0)

Values are presented as number (%).
mHSPC, metastatic hormone-sensitive prostate cancer; NGI, next-generation imaging; ADT, androgen-deprivation therapy; ARPI, androgen receptor pathway inhibitor; PSMA PET, prostate-specific membrane antigen positron emission tomography.

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Table 3. Consensus on general mHSPC management

Pre-determined key question (yes/no)	Questions and response options	Completed	
		First round (n=23)	Second round (n=23)
Yes	1. What is your general treatment recommendation for the majority of patients with mHSPC?	Strong consensus	
	1. Combination therapy (ADT plus additional systemic therapy and/or local radiotherapy)	100.0% (23)	
	2. ADT alone	0.0% (0)	
Yes	2. What is your general treatment recommendation for the majority of patients with synchronous high-volume (on conventional imaging or unequivocal on NGI) mHSPC?	Strong consensus	
	1. Combination therapy (ADT plus additional systemic therapy)	100.0% (23)	
	2. ADT alone	0.0% (0)	
Yes	3. What is your general treatment recommendation for the majority of patients with synchronous low-volume (on conventional imaging or unequivocal on NGI) mHSPC?	Consensus	
	1. Combination therapy (ADT plus additional systemic therapy and/or local radiotherapy)	87.0% (20)	
	2. ADT alone	13.0% (3)	
Yes	4. What is your general treatment recommendation for the majority of patients with metachronous high-volume (on conventional imaging or unequivocal on NGI) mHSPC?	Strong consensus	
	1. Combination therapy (ADT plus additional systemic therapy)	100.0% (23)	
	2. ADT alone	0.0% (0)	
No	5. What is your general treatment recommendation for the majority of patients with metachronous low-volume (on conventional imaging or unequivocal on NGI) mHSPC?	Strong consensus	
	1. Combination therapy (ADT plus additional systemic therapy and/or local radiotherapy)	95.7% (22)	
	2. ADT alone	4.3% (1)	
	3. RT alone	0.0% (0)	
	4. ADT plus RT	0.0% (0)	
Yes	6. What is your general systemic treatment recommendation in addition to ADT for the majority of mHSPC patients?	Strong consensus	
	1. ARPI	100.0% (23)	
	2. NSAA	0.0% (0)	
	3. Chemotherapy	0.0% (0)	
	4. I usually do not recommend additional systematic treatment	0.0% (0)	

Values are presented as % (number).
mHSPC, metastatic hormone-sensitive prostate cancer; ADT, androgen-deprivation therapy; NGI, next-generation imaging; RT, radiotherapy; ARPI, androgen receptor pathway inhibitor; NSAA, non-steroidal anti-androgen.

(by 91.3% of panelists) if all options were to be approved and reimbursed. For low-volume disease patients per conventional imaging but high-volume disease per next-generation imaging (NGI), most panelists (78.3%) recommended treating these patients as per a high-volume disease diagnosis.

Panelists reached consensus regarding treatment recommendations for patients with synchronous low-volume mHSPC. This included no recommendation for triplet therapy, irrespective of a decision about local radiation therapy, and radiation therapy of the primary tumor in addition to systemic therapy.

Panelists also reached consensus on concurrent administration of triplet therapy if all treatment options are approved and reimbursed.

Two questions on the recommendation of adding docetaxel alone to ADT were pre-determined as key questions where panelists achieved strong consensus. All panelists voted against adding docetaxel alone for low-volume or high-volume mHSPC, when assuming ARPI or triplet therapy is available.

Table 4. Consensus on synchronous and metachronous mHSPC management

Pre-determined key question (yes/no)	Questions and response options	Completed	
		First round (n=23)	Second round (n=23)
No	7. In which patients with synchronous mHSPC that are chemotherapy fit do you recommend the sequential use of ADT/docetaxel+ARPI in the current drug approval and reimbursement environment?	No consensus	Consensus
	1. In the majority of patients, independent of disease volume	13.0% (3)	0.0% (0)
	2. Only in high-volume patients	60.9% (14)	87.0% (20)
	3. I usually do not recommend this combination	26.1% (6)	13.0% (3)
No	8. In which patients with synchronous mHSPC that are chemotherapy fit do you recommend the triplet therapy (ADT/docetaxel+ARPI) if all treatment options are approved and reimbursed? (triplet therapy refers to both concurrent or sequential use)	Consensus	
	1. In the majority of patients, independent of disease volume	8.7% (2)	
	2. Only in high-volume patients	82.6% (19)	
	3. I usually do not recommend this combination	8.7% (2)	
No	9. In which patients with metachronous mHSPC that are chemotherapy fit do you recommend the sequential use of ADT/docetaxel+ARPI in the current drug approval and reimbursement environment?	No consensus	Consensus
	1. In the majority of patients independent of disease volume	13.0% (3)	0.0% (0)
	2. Only in high-volume patients	47.8% (11)	78.3% (18)
	3. I usually do not recommend this combination	39.1% (9)	21.7% (5)
No	10. In which patients with metachronous mHSPC that are chemotherapy fit do you recommend the triplet therapy (ADT/docetaxel+ARPI) if all treatment options are approved and reimbursed? (triplet therapy refers to both concurrent or sequential use)	No consensus	Strong consensus
	1. In the majority of patients, independent of disease volume	13.0% (3)	0.0% (0)
	2. Only in high-volume patients	69.6% (16)	100.0% (23)
	3. I usually do not recommend this combination	17.4% (4)	0.0% (0)
No	11. In the majority of patients with synchronous high-volume (on conventional imaging or unequivocal on NGI with corresponding sclerotic lesions on CT if PSMA PET) mHSPC, what is your preferred systemic treatment in addition to ADT in the current drug approval and reimbursement environment?	No consensus	Strong consensus
	1. ARPI as sole additional therapy	65.2% (15)	91.3% (21)
	2. Docetaxel as sole additional therapy	8.7% (2)	0.0% (0)
	3. Docetaxel plus ARPI (sequential use)	26.1% (6)	8.7% (2)
	4. ADT alone	0.0% (0)	0.0% (0)
No	12. In the majority of patients with synchronous high-volume (on conventional imaging or unequivocal on NGI with corresponding sclerotic lesions on CT if PSMA PET) mHSPC, what is your preferred systemic treatment in addition to ADT if all treatment options are approved and reimbursed?	No consensus	Strong consensus
	1. ARPI as sole additional therapy	39.1% (9)	8.7% (2)
	2. Docetaxel as sole additional therapy	4.3% (1)	0.0% (0)
	3. Docetaxel plus ARPI (either concurrent or sequential use)	56.5% (13)	91.3% (21)
	4. ADT alone	0.0% (0)	0.0% (0)
No	13. What is your recommended treatment strategy in the majority of patients with mHSPC that have low-volume disease by conventional imaging but high-volume by NGI?	No consensus	Consensus
	1. Treat as per high-volume	69.6% (16)	78.3% (18)
	2. Treat as per low-volume	30.4% (7)	21.7% (5)

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Table 4. Continued

Pre-determined key question (yes/no)	Questions and response options	Completed	
		First round (n=23)	Second round (n=23)
No	14. In which patients with synchronous low-volume (on conventional imaging) mHSPC do you recommend the triplet systemic therapy (including sequential use), irrespective of a decision about local radiation therapy?	No consensus	Strong consensus
	1. In the majority of patients	13.0% (3)	0.0% (0)
	2. In low-volume but "borderline" high risk features (one or more these factors, e.g., Gleason 8–10, 3–4 bone metastases, extensive LN, disease cannot be covered by SBRT)	26.1% (6)	0.0% (0)
	3. I do not recommend triplet therapy in these patients	60.9% (14)	100.0% (23)
No	15. In the majority patients with synchronous low-volume mHSPC where you have decided for the systemic therapy (ADT+ARPI±docetaxel), do you recommend radiation therapy of the primary tumor in addition?	No consensus	Consensus
	1. Yes	56.5% (13)	78.3% (18)
	2. No	43.5% (10)	21.7% (5)
No	16. If you recommend triplet therapy (ADT/docetaxel+ARPI) in patients with mHSPC, what is your preferred strategy if all treatment options are approved and reimbursed?	No consensus	Consensus
	1. Sequential administration (docetaxel completed first, as for TITAN, ARCHES)	30.4% (7)	13.0% (3)
	2. Concurrent administration (as for ARASENS, PEACE-1, ENZAMET)	69.6% (16)	87.0% (20)
Yes	17. In patients with low-volume mHSPC, do you recommend the addition of docetaxel alone to ADT (assuming that ARPI or triplet systemic therapy is available)?	Strong consensus	
	1. Yes, in the majority of patients	0.0% (0)	
	2. No	100.0% (23)	
Yes	18. In patients with high-volume mHSPC, do you recommend the addition of docetaxel alone to ADT (assuming that ARPI or triplet systemic therapy is available)?	No consensus	Strong consensus
	1. Yes, in the majority of patients	30.4% (7)	0.0% (0)
	2. No	69.6% (16)	100.0% (23)

Values are presented as % (number).
mHSPC, metastatic hormone-sensitive prostate cancer; ADT, androgen-deprivation therapy; ARPI, androgen receptor pathway inhibitor; NGI, next-generation imaging; CT, computed tomography; PSMA PET, prostate-specific membrane antigen positron emission tomography; LN, lymph node; SBRT, stereotactic body radiotherapy.

3) Management of frail patients

Consensus was reached for the question regarding frail (geriatric) patients during the second survey round. Most panelists (82.6%) do not perform geriatric assessments in daily practice (Table 5).

4) Genomic profiling

Consensus was reached on all four questions during the second survey round (Table 6).

Most panelists (87.0%) recommended next-generation sequencing (NGS) in a minority of selected patients, and most (95.7%) agreed that information on genomic profiling would not influence their decision for first-line treatment in mHSPC. All panelists favored ADT+ARPI for treating high-volume mHSPC patients with the speckle-type poxvirus and zinc finger protein (SPOP) mutation. Most panelists (87.0%) preferred tissue biopsy alone to liquid biopsy for an NGS test.

5) Management of monitoring

Consensus was reached on two of three questions during the first survey round and on the remaining question in the second survey round (Table 7).

Under the current reimbursement environment in South Korea, 82.6% of panelists recommended regular imaging every 3 months, regardless of PSA in mHSPC patients on intensive systemic therapy. However, when provided with the hypothetical scenario that all options are eligible for reimbursement for this patient population, 87.0% of panelists recommend regular imaging every 6–12 months regardless

Table 5. Consensus on management of frail patients

Pre-determined key question (yes/no)	Questions and response options	Completed	
		First round (n=23)	Second round (n=23)
No	19. In daily clinical practice and outside of clinical trials, do you perform (not only recommend) geriatric assessments by validated instruments (e.g., G8/miniCOG/CGA) in the majority of patients with mHSPC who are ≥75 years?	No consensus	Consensus
	1. Yes, in the majority of patients	17.4% (4)	13.0% (3)
	2. Yes, but only if red flag issues are raised during consultation (frailty, cognitive issues, heart disease, and significant comorbidity)	34.8% (8)	4.3% (1)
	3. No	47.8% (11)	82.6% (19)

Values are presented as % (number).
G8, geriatric 8; CGA, comprehensive geriatric assessment; mHSPC, metastatic hormone-sensitive prostate cancer.

Table 6. Consensus on mHSPC management regarding genomic profiling

Pre-determined key question (yes/no)	Questions and response options	Completed	
		First round (n=23)	Second round (n=23)
No	20. In patients with (synchronous or metachronous) mHSPC, do you recommend NGS?	No consensus	Consensus
	1. Yes, in the majority of patients	39.1% (9)	13.0% (3)
	2. Yes, more than half of patients	4.3% (1)	0.0% (0)
	3. Yes, only in a minority of selected patients	52.2% (12)	87.0% (20)
	4. I usually do not recommend NGS	4.3% (1)	0.0% (0)
No	21. Outside a clinical trial, would the information on tumor genomic profiling (primary tumor or biopsy of metastatic lesion) influence your decision for first-line treatment of mHSPC in the majority of patients, if available without restrictions?	No consensus	Strong consensus
	1. Yes	26.1% (6)	4.3% (1)
	2. No	73.9% (17)	95.7% (22)
No	22. In the majority of patients with high-volume mHSPC and presence of a pathogenic SPOP mutation, what is your recommended systemic therapy?	No consensus	Strong consensus
	1. ADT alone	0.0% (0)	0.0% (0)
	2. ADT plus ARPI	65.2% (15)	100.0% (23)
	3. ADT plus docetaxel	17.4% (4)	0.0% (0)
	4. ADT/docetaxel plus ARPI	17.4% (4)	0.0% (0)
No	23. For the majority of patients with mHSPC, what is your preferred biopsy method for metastatic lesion?	No consensus	Consensus
	1. Tissue biopsy alone	73.9% (17)	87.0% (20)
	2. Liquid biopsy alone	17.4% (4)	13.0% (3)
	3. Tissue biopsy plus liquid biopsy	8.7% (2)	0.0% (0)

Values are presented as % (number).
mHSPC, metastatic hormone-sensitive prostate cancer; NGS, next-generation sequencing; SPOP, speckle-type poxvirus and zinc finger protein; ADT, androgen-deprivation therapy; ARPI, androgen receptor pathway inhibitor.

of PSA (consensus reached during the second survey round). Most panelists (87.0%) preferred conventional imaging over other methods.

6) Management of oligometastatic mHSPC

Consensus was reached on one question during the first survey round and on six questions during the second survey round. Consensus was not reached on three questions across both survey rounds (Table 8).

Consensus was reached on a pre-determined key question about systemic therapy recommendations for patients with low-volume/oligometastatic synchronous mHSPC and prostate-specific membrane antigen (PSMA) positron emission tomography (PET)-positive retroperitoneal lymph nodes,

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Table 7. Consensus on mHSPC management of monitoring

Pre-determined key questions (yes/no)	Questions and response options	Completed	
		First round (n=23)	Second round (n=23)
No	24. What ongoing monitoring by imaging do you recommend for the majority of patients with mHSPC on intensive systemic therapy (assuming that they do not develop new symptoms) in the current reimbursement environment?	Consensus	
	1. PSA-prompted and no imaging until confirmed PSA progression	8.7% (2)	
	2. Regular imaging, e.g., every 3 months, regardless of PSA	82.6% (19)	
	3. Regular imaging, e.g., every 6–12 months, regardless of PSA	8.7% (2)	
No	25. What ongoing monitoring by imaging do you recommend for the majority of patients with mHSPC on systemic therapy (assuming that they do not develop new symptoms) if all the options are reimbursed?	No consensus	Consensus
	1. PSA-prompted and no imaging until confirmed PSA progression	17.4% (4)	8.7% (2)
	2. Regular imaging, e.g., every 3 months, regardless of PSA	26.1% (6)	4.3% (1)
	3. Regular imaging, e.g., every 6–12 months regardless of PSA	56.5% (13)	87.0% (20)
No	26. For the majority of patients, what is your preferred imaging modality of patients with mHSPC for treatment monitoring?	Consensus	
	1. Conventional imaging	87.0% (20)	
	2. Whole-body MRI	0.0% (0)	
	3. PSMA PET	13.0% (3)	

Values are presented as % (number).
mHSPC, metastatic hormone-sensitive prostate cancer; PSA, prostate-specific antigen; MRI, magnetic resonance imaging; PSMA PET, prostate-specific membrane antigen positron emission tomography.

recommending systemic therapy with ADT+ARPI.

Consensus was not reached on basing treatment recommendations in low-volume/oligometastatic synchronous mHSPC on conventional imaging only (without NGI) when NGI is readily available (39.1% of panelists voted that it is not appropriate).

Regarding the treatment recommendation for patients with low-volume/oligometastatic synchronous mHSPC and 1–3 bone lesions on NGI, consensus was reached on systemic therapy+local treatment of the primary and metastases-directed therapy (MDT). All 21 panelists that selected these responses chose ADT+ARPI as the specific treatment recommendation. Strong consensus (91.3% of panelists) was reached for radiation therapy for the primary tumor in this population.

No consensus was reached for general treatment recommendations for low-volume/oligometastatic synchronous mHSPC patients who have positive retroperitoneal lymph nodes (e.g., 1–3 lesions on PSMA PET). However, follow-up questions revealed that all panelists recommended ADT+ARPI for systemic therapy, and 93.3% recommended radiation therapy for local treatment.

Treatment recommendations for low-volume/oligometastatic metachronous mHSPC (e.g., 3 bone lesions on NGI) were systemic therapy+MDT (87.0% of panelists), with ADT+ARPI as the preferred systemic therapy (100.0% of panelists).

7) Key recommendations

See Table 9 for key recommendations.

DISCUSSION

The current study established consensus recommendations for evidence-based optimal treatment of mHSPC patients in South Korea, reflecting the local treatment environment. Twenty-three urologists from South Korea completed two rounds of a modified Delphi panel survey, consisting of 36 questions on six topics regarding mHSPC management. Consensus was reached for all pre-determined key questions covering management of general, synchronous and metachronous, and oligometastatic mHSPC. Responses were mostly consistent with results from APCCC 2022, where a panel of 105 international prostate cancer experts voted on consensus questions regarding the management of advanced prostate cancer [17].

Strong consensus was reached on the significance of TI in mHSPC, particularly with an ARPI, regardless of the volume of disease or disease type (metachronous or synchronous). Despite universal agreement on the use of ADT+ARPI and clinical trial evidence supporting its efficacy [9-11], real-world practice suggests that ADT monotherapy

Table 8. Consensus on management of oligometastatic mHSPC

Pre-determined key questions (yes/no)	Questions and response options	Completed	
		First round (n=23)	Second round (n=23)
No	27. Is it appropriate to base treatment recommendations in low-volume/oligometastatic synchronous mHSPC on conventional imaging only without NGI when NGI is readily available?	No consensus	No consensus
	1. Yes	52.2% (12)	60.9% (14)
	2. No	47.8% (11)	39.1% (9)
No	28. For the majority of patients with low-volume/oligometastatic synchronous mHSPC and 1–3 bone lesions on NGI, what is your treatment recommendation?	No consensus	Consensus
	1. Systemic therapy alone	8.7% (2)	8.7% (2)
	2. Systemic therapy plus local treatment of the primary	34.8% (8)	8.7% (2)
	3. Systemic therapy plus local treatment of the primary and MDT	56.5% (13)	82.6% (19)
	4. Local treatment of the primary and MDT without systemic therapy	0.0% (0)	0.0% (0)
No	28-1. If you voted for systemic therapy plus local treatment for the majority of patients with low-volume/oligometastatic synchronous mHSPC (e.g., 1–3 bone lesions on NGI), what is your treatment recommendation?	Strong consensus	Strong consensus
	1. ADT plus ARPI	95.2% (20)	100.0% (21)
	2. ADT plus docetaxel	4.8% (1)	0.0% (0)
	3. ADT/docetaxel plus ARPI	0.0% (0)	0.0% (0)
	4. ADT alone	0.0% (0)	0.0% (0)
No	28-2. If you voted for systemic therapy alone for the majority of patients with low-volume/oligometastatic synchronous mHSPC (e.g., 1–3 bone lesions on NGI), what is your treatment recommendation?	Strong consensus	No consensus
	1. ADT plus ARPI	100% (2)	50.0% (1)
	2. ADT plus docetaxel	0.0% (0)	0.0% (0)
	3. ADT/docetaxel plus ARPI	0.0% (0)	0.0% (0)
	4. ADT alone	0.0% (0)	50.0% (1)
No	29. For the majority of patients with low-volume/oligometastatic synchronous mHSPC (e.g., 1–3 bone lesions on NGI), what is your treatment recommendation regarding the primary tumor?	Strong consensus	
	1. Radiation therapy	91.3% (21)	
	2. Surgery	8.7% (2)	
No	30. For the majority of patients with low-volume/oligometastatic synchronous mHSPC and PSMA PET-positive retroperitoneal lymph nodes (e.g., 1–3 lesions), what is your treatment recommendation?	No consensus	No consensus
	1. Systemic therapy alone	13.0% (3)	4.3% (1)
	2. Systemic therapy plus local treatment of the primary	43.5% (10)	30.4% (7)
	3. Systemic therapy plus local treatment of the primary and MDT	43.5% (10)	65.2% (15)
	4. Local treatment of the primary and MDT without systemic therapy	0.0% (0)	0.0% (0)
Yes	30-1. If you recommend systemic therapy for the majority of patients with low-volume/oligometastatic synchronous mHSPC and PSMA PET-positive retroperitoneal lymph nodes (e.g., 1–3 lesions), what is your treatment recommendation?	Strong consensus	Strong consensus
	1. ADT plus ARPI	100.0% (23)	100.0% (23)
	2. ADT plus docetaxel	0.0% (0)	0.0% (0)
	3. ADT/docetaxel plus ARPI	0.0% (0)	0.0% (0)
	4. ADT alone	0.0% (0)	0.0% (0)

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Table 8. Continued

Pre-determined key questions (yes/no)	Questions and response options	Completed	
		First round (n=23)	Second round (n=23)
No	30-2. If you voted for MDT of the retroperitoneal lymph nodes (e.g., 1–3 lesions), what is your local treatment recommendation in the majority of patients?	Strong consensus	Strong consensus
	1. Radiation therapy	90.0% (9)	93.3% (14)
	2. Surgery	10.0% (1)	6.7% (1)
No	31. For the majority of patients with low-volume/oligometastatic metachronous mHSPC (e.g., 3 bone lesions on NGI), what is your treatment recommendation?	No consensus	Consensus
	1. Systemic therapy alone	34.8% (8)	13.0% (3)
	2. Systemic therapy plus MDT	65.2% (15)	87.0% (20)
	3. MDT without systemic therapy	0.0% (0)	0.0% (0)
Yes	31-1. If you recommend systemic therapy in the majority of patients with low-volume/oligometastatic metachronous mHSPC (e.g., 3 bone lesions on NGI), what is your treatment recommendation?	Strong consensus	Strong consensus
	1. ADT plus ARPI	100.0% (23)	100.0% (23)
	2. ADT plus docetaxel	0.0% (0)	0.0% (0)
	3. ADT/docetaxel plus ARPI	0.0% (0)	0.0% (0)
	4. ADT alone	0.0% (0)	0.0% (0)

Values are presented as % (number).
mHSPC, metastatic hormone-sensitive prostate cancer; NGI, next-generation imaging; MDT, metastases-directed therapy; ADT, androgen-deprivation therapy; ARPI, androgen receptor pathway inhibitor; PSMA PET, prostate-specific membrane antigen positron emission tomography.

Table 9. Key treatment recommendations

Recommendations	Agreement by panelist
Combination therapy vs. ADT alone	
Consensus was reached on recommending ADT intensification over ADT alone, irrespective of disease volume or whether the disease is metachronous or synchronous	Synchronous HV: 100.0% Synchronous LV: 87.0% Metachronous HV: 100.0% Metachronous LV: 95.7%
For treatment intensification, ARPI in addition to ADT is recommended by all panelists for the majority of patients with mHSPC	100.0%
Docetaxel addition	
Docetaxel alone is not recommended by any panelists for addition to ADT when an ARPI is available for intensification	100.0%
Pathogenic SPOP mutation	
For patients with high-volume mHSPC and a pathogenic SPOP mutation, ADT+ARPI is recommended by all panelists over docetaxel doublet or triplet therapy as the systemic therapy	100.0%
Monitoring	
Consensus was reached on recommending regular imaging every 3 months, regardless of PSA levels, under the current local reimbursement guidelines that were based on clinical trials	82.6%
If there are no strict reimbursement guidelines, the recommendation changes to regular imaging every 6–12 months, regardless of PSA levels	87.0%
Oligometastatic mHSPC	
ADT+ARPI is the most recommended systemic treatment option by all panelists	100.0%

ADT, androgen-deprivation therapy; HV, high-volume; LV, low-volume; ARPI, androgen receptor pathway inhibitor; mHSPC, metastatic hormone-sensitive prostate cancer; SPOP, speckle-type poxvirus and zinc finger protein; PSA, prostate-specific antigen.

is still a widely used treatment option for mHSPC globally [22]. Urologists in South Korea clearly recommend combination therapy over ADT monotherapy and, as such, should strongly consider this in daily practice.

There was a strong consensus that docetaxel alone should not be prioritized in addition to ADT when an ARPI is available. Triplet therapy (ADT/docetaxel+ARPI) was recommended only for high-volume patients eligible for chemotherapy. However, the preference for triplet or doublet systemic treatments in synchronous high-volume mHSPC varied depending on drug approval and reimbursement scenarios. This highlights how the limited availability of triplet therapy in South Korea, due to drug approval status and reimbursement criteria, significantly influences physicians' treatment decisions.

Regarding frail (geriatric) patients, most panelists (82.6%) do not perform geriatric assessments in daily practice. While guidelines recommend performing a geriatric assessment [13], routinely implementing this is unrealistic in the local treatment environment, where physicians typically see >50 outpatients per day and may not have time for routine geriatric diagnostics.

The results also support tailored treatment strategies according to the pathogenic mutation status in mHSPC patients. Tumor genomic profiling of mHSPC patients could help identify potentially actionable genetic alterations in patients with advanced prostate cancer [23]. ADT+ARPI was recommended by all panelists over docetaxel doublet or triplet therapy as the systemic therapy for patients with high-volume mHSPC with a pathogenic SPOP mutation. The National Comprehensive Cancer Network® guidelines now recommend genetic testing for all patients with metastatic prostate cancer [14], with similar recommendations from the European Society for Medical Oncology [24,25] and the European Association of Urology [13] guidelines. However, genomic profiling was only recommended for select patients in the current study, probably because gene-based targeted therapies remain unavailable, except poly (ADP-ribose) polymerase (PARP) inhibitor.

Current guidelines are ambiguous about plans for monitoring treatment responses but recommend individualizing follow-up plans based on disease stage, prior symptoms, prognostic factors, and therapies administered [17]. Therefore, the status and ideal frequency of monitoring methods for mHSPC in South Korea was investigated in the current study. For most mHSPC patients on intensive systemic therapy, regular imaging (regardless of PSA) every 3 months in the current reimbursement environment was recommended. This is at a higher frequency than every 6–12 months, which 50.0% of panelists at APCCC 2022 recommended for patients on systemic therapy [17]. However, in the (hypothetical) scenario where all mHSPC monitoring options are reimbursed, panelists recommended ongoing monitoring by imaging every 6–12 months for patients on systemic therapy. Thus, current South Korean reimbursement guidelines for regular imaging in monitoring of mHSPC may not be optimal and therefore need to be revisited and revised. Additionally, despite the evolving imaging technology for treatment monitoring, most panelists still preferred conventional imaging over other methods, similar to the results of APCCC 2022 [17]. This might be due to the relatively high cost of NGI and because it is only available at a limited number of centers in South Korea.

Oligometastatic mHSPC management was the only topic with questions that failed to reach consensus after two rounds of survey. Guidance on this topic remained unclear, given the dearth of evidence on effective therapies and that the oligometastatic stage is not well-defined [26]. The impact of imaging modalities on treatment decisions for low-volume/oligometastatic synchronous mHSPC also remains unclear. Though more panelists (60.9%) agreed that it was appropriate to base treatment recommendations only on conventional imaging without NGI, even when NGI is readily available, many (39.1%) disagreed. Despite the lack of consensus, combination therapy of ADT+ARPI was still the most recommended systemic treatment by all panelists.

The main strength of this study is that it resulted in a set of thorough, up-to-date consensus recommendations for mHSPC management in South Korea. This study also addressed a main limitation of the survey administered at APCCC 2022: the assumption that all diagnostic and therapeutic options are available. Approval and reimbursement of treatment options (despite evidence of efficacy) could influence clinicians' real-world decision-making, as patients may face challenges accessing some treatments. Here, we accounted for both the current healthcare environment and ideal scenario (where all options are approved and reimbursed).

While we included panelists from across South Korea who treat a wide range of patients and clinical experiences, one potential limitation is that the final recommendations may not accurately reflect all patient diversity. That is, the panel only comprised urologists; the inclusion of oncologists or private sector physicians may have yielded different approaches to treating mHSPC patients. Therefore, the results may not fully reflect real-world clinical practice (particularly regarding systemic therapy and radiotherapy), which is often carried out through a multidisciplinary approach. Expert consultative bodies in Korea are providing opinions on the

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necessity of insurance coverage. Therefore, we hope these recommendations will be used as reference material in terms of reflecting the opinions of experts in the future expansion of domestic insurance coverage.

CONCLUSIONS

This modified Delphi consensus established local expert agreement on several controversial aspects of mHSPC management. While the findings may not fully reflect current reimbursement constraints in South Korea, they provide valuable insights that can inform future clinical decision-making and support discussions around revising reimbursement criteria. By aligning expert consensus with evidence-based practice, this study contributes to bridging the gap between optimal care recommendations and real-world clinical implementation.

CONFLICTS OF INTEREST

Chang Wook Jeong received research grants from Intuitive Surgical and Medtronic and has received honoraria for lectures for Astellas, Ipsen, and Johnson & Johnson. The other authors have nothing to disclose.

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