



## Lifestyle aspects in a contemporary middle-European cohort of patients undergoing androgen deprivation therapy for advanced prostate cancer: data from the non-interventional LEAN study

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### Abstract

Androgen deprivation therapy (ADT) in men with prostate cancer (PCa) is associated with significant side effects. With the transition of PCa from a foudroyant course to a chronic disease, managing these side effects has become increasingly important. There is growing evidence that nutritional changes and physical activity are beneficial in these patients. Here we examine the impact of written patient information on the physical activity and dietary habits of PCa patients receiving ADT and behaviour changes between baseline and 1 year, in the open-label, non-interventional LEAN study. In total, 959 patients with advanced hormone-sensitive PCa requiring ADT with the Leuprorelin Sandoz<sup>®</sup> implant were included from January 2014 to July 2015 and followed for  $\geq 12$  months. At the start of the study, urologists received a questionnaire concerning the written information provided to patients regarding their disease, patient advocacy groups, diet and physical activity. Patients received a questionnaire on their dietary habits and physical activity at the start and end of the study. Urologists from 147 study centres and 540 patients responded to the questionnaires. While 69 % of these patients received disease-specific information, only 30 % and 17 % received information regarding nutrition and physical activity, respectively. The majority of urologists estimate that their patients rarely or never follow guidance on nutrition or physical activity, yet > 90 % of patients indicate they would make use of this information, if provided. Few patients showed behavioural changes between baseline and 1 year without evident differences between patients that received information and those that did not.

**Key words:** Prostate cancer: Leuprorelin: Androgen deprivation therapy: Lifestyle factors: Nutrition

Androgen deprivation therapy (ADT) using luteinising hormone-releasing hormone (LHRH) agonists represents the standard of care in men with advanced prostate cancer (PCa), suppressing blood testosterone to castrate levels in the vast majority of patients<sup>(1,2)</sup>. While metastatic PCa has been the primary indication for ADT for several decades, the introduction of prostate-specific antigen-based early detection, along with local therapy by radical prostatectomy and/or radiation therapy, has resulted in a significant migration of ADT use to earlier stages of the disease. Consequently, PCa has become a chronic disease with many men undergoing long-term ADT.

Leuprorelin acetate, a synthetic analogue of LHRH, is the most widely prescribed compound of its class<sup>(1–4)</sup>. Two unique slow-release pharmaceutical forms of leuprorelin acetate (Leuprorelin Sandoz<sup>®</sup>, Leuprone<sup>®</sup> HEXAL<sup>®</sup>; 1-month and 3-month implant) were first approved in 2007<sup>(5)</sup>. The LEAN study ([www.germanctr.de](http://www.germanctr.de), trial-ID DRKS00005643, ‘Observation of Leuprone<sup>®</sup> HEXAL<sup>®</sup> in treatment practice. Non-interventional study on effectiveness and tolerability and on the influence of anamnestic factors’) is a non-interventional German cohort study investigating the use of the Leuprorelin Sandoz<sup>®</sup> implant in routine clinical practice. The study was designed to extend existing

**Abbreviations:** ADT, androgen deprivation therapy; LHRH, luteinising hormone-releasing hormone; PCa, prostate cancer.

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knowledge on the efficacy and tolerability of Leuprorelin Sandoz<sup>®</sup> implant in men with PCa and to examine the influence of anamnestic factors and lifestyle on the course of the disease<sup>(4)</sup>.

The testosterone depletion resulting from ADT is well known to affect patient activity and body composition and might impact glucose tolerance by having pro-diabetic effects. Lean mass decreases by 2–4% and fat mass increases by 14% in ADT-treated men with PCa after 36 weeks<sup>(6–8)</sup>. Furthermore, lean mass changes affect the limbs more than the trunk, which may exacerbate physical function decline<sup>(6,8)</sup>. Indeed, ADT leads to a decline in lower limb muscle function, affecting muscles involved in support, walking and balance<sup>(9)</sup>.

Increased fat mass and decreased lean mass may lead to sarcopenic obesity, which is associated with an increase in obesity-related comorbidities and all-cause mortality<sup>(10,11)</sup>. Although ADT is also associated with an increased risk of cardiovascular disease (CVD), studies have shown this is not accompanied by an overall increased risk of cardiovascular mortality, except in some patients with previous congestive heart failure, myocardial infarction or metabolic syndrome<sup>(1)</sup>.

There is evidence that nutritional changes and increased physical activity would be highly beneficial to this patient cohort<sup>(10,12)</sup>. Nutritional changes can allay ADT-related adverse changes by helping reduce body fat; however, the benefits for lean mass are less pronounced and protein intake may need to be optimised for lean mass preservation<sup>(8,11)</sup>. Physical activity improves quality of life (QoL) and reduces ADT-related side effects such as cancer-related fatigue and poorer physical function<sup>(13)</sup>. Multi-modal aerobic and resistance training is needed to stimulate lipolysis and muscle protein synthesis for the prevention of lean mass loss and fat mass increase<sup>(10,11)</sup>. Consequently, expert panels and guidelines recommend lifestyle measures to minimise the side effects associated with ADT<sup>(1,2,14,15)</sup>.

This raises the question of how best to educate PCa patients receiving ADT to adopt nutritional changes and increase physical activity. Many studies have shown that providing adequate information to PCa patients receiving hormone therapy can improve healthy behaviour, self-care ability and QoL<sup>(16–18)</sup>. Written information is a cost-effective way to complement physicians' verbal advice and enables patients to better manage their health, particularly when part of an information support program<sup>(18,19)</sup>.

This sub-analysis from the LEAN study examines the impact of written patient information materials on the physical activity and dietary habits of PCa patients receiving ADT, as perceived by the patient and their urologist. Behavioural changes following lifestyle recommendations and changes in patient diet and physical activity during the 1-year LEAN study are also reported.

## Materials and methods

### Ethics approval

The authors declare compliance with acknowledged ethical standards and good clinical practice. IRB approval was obtained, and all patients and physicians provided informed consent prior to completing the questionnaire.

This study was conducted according to the guidelines laid down in the Declaration of Helsinki, and all procedures involving

human subjects were approved by the ethics committee of the Scientific Medical Lead (BSD), that is, the Ethics Committee of the Bavarian Chamber of Physicians, Munich, Germany, and subsequently by the ethics committees of all study sites.

### Study description

The LEAN study is an open-label, multicentre, non-interventional German cohort study<sup>(4)</sup>. The primary objective was to extend existing knowledge on the effects and tolerability of the Leuprorelin Sandoz<sup>®</sup> solid implant in daily clinical practice. Secondary objectives were to investigate associations between various anamnestic factors and the course of prostate-specific antigen and testosterone in a real-world setting and to capture comorbidities and lifestyle changes of patients receiving leuprorelin solid implant. The study was initiated in 2014 and is still ongoing and thus permits corroboration of earlier findings and provides valuable information on changes in indications for ADT and co-medication over time. The current study is a sub-analysis from the LEAN study, examining the impact of written patient information materials on the physical activity and dietary habits of PCa patients receiving ADT.

### Patient selection criteria

The study included patients with advanced hormone-sensitive PCa, in whom treatment with Leuprorelin Sandoz<sup>®</sup> (1 month or 3 months) was planned in accordance with the summary of product characteristics. Further inclusion criteria were life expectancy > 12 months and an Eastern Cooperative Oncology Group performance status of 0–2. There was no upper age limit. Patients were eligible to receive LHRH agonist therapy for < 6 months before recruitment; concomitant therapy with an LHRH antagonist, abiraterone acetate, third-generation antiandrogens (enzalutamide) or chemotherapy were exclusion criteria. Patients receiving local or palliative radiotherapy were eligible. Patients from the modified full analysis set who responded to the questionnaires at baseline and at the end of study were included in this sub-analysis.

### Patient assessment and data collection

Before starting patient enrolment, urologists at all centres received a questionnaire addressing the written information provided to patients, including disease-specific information, local patient advocacy groups and lifestyle issues, such as nutrition and physical activity. The questionnaire included questions about all patients treated by the urologist at the centre and was not restricted to those taking leuprorelin or who were enrolled in the LEAN study.

All patients received a questionnaire on their dietary habits and physical activity at baseline and at the end of study (12 months). Patients were categorised according to how often they undertook sport/physical activity (never, rarely, at least once a week and more than once a week, daily)<sup>(20,21)</sup> and how frequently they consume fish (< 2 or ≥ 2 times a week)<sup>(21,22)</sup>, poultry (< 2 or ≥ 2 times a week)<sup>(23)</sup>, dairy products (< 1 or ≥ 1 time a day)<sup>(21)</sup>, fruit and vegetables (almost daily)<sup>(21,24)</sup> and red meat (< 3 or ≥ 3 times a week)<sup>(25)</sup>. The questionnaires



were not validated, due to an absence of official validation methods specific to these questionnaires. The questionnaires are included in Supplementary Appendices 1 and 2.

### Statistical analysis

Patient characteristics, medical history and demographics were analysed using descriptive statistics and presented as mean  $\pm$  standard deviations (SD) or frequency categories, unless stated otherwise. Percentages for categories in this paper relate to the number of patients or centres providing information. Shift tables include data from patients providing information both at baseline and at the end of observation. Odds ratios (OR) were calculated to assess the effect of providing written information on nutrition and physical activity on patient behaviour at the end of the study. Further details on statistics, including analysis of the efficacy of the Leuprorelin Sandoz<sup>®</sup> implant, are described elsewhere<sup>(4)</sup>.

## Results

### Baseline characteristics

Between January 2014 and July 2015, 959 PCa patients with a need for ADT, as decided by a urologist, were screened at 150 study centres in Germany<sup>(4)</sup>. The mean age of the study population was 75 years. Patients from the modified full analysis set responding to the questionnaires at baseline and end of study were considered for this analysis ( $n$  540 in total; the number of patients responding to each individual question varied) (online Supplementary Fig. S1). At the time of data cut-off, the mean time since PCa diagnosis was 25.8 months (SD: 46.7 months). Approximately half of patients (52%) had concomitant CVD and 16% had endocrine/metabolic disorders at baseline. One-third of patients had no documented relevant comorbidities at baseline. The majority of patients had a baseline Eastern Cooperative Oncology Group performance status of 0 (59.9%) or 1 (33.6%) and 6.5% had an Eastern Cooperative Oncology Group performance status of 2. Further details on patient demographics and disease characteristics at baseline have been previously reported<sup>(4)</sup>.

### Physician questionnaire

Urologists ( $n$  147 study centres) reported comprehensive patient counselling, comprising all aspects of the disease and adequate therapies, information regarding local patient advocacy groups and, less frequently, on lifestyle issues (Table 1). It is of note that (1) these statements are based upon questions regarding the usual procedure at their study centre and (2) the questions did not address information provided verbally, but rather the transfer of additional, mostly written material (i.e. flyers and pamphlets). The physician questionnaire indicates that there is significant variation between study centres in the quantity and scope of information provided to PCa patients undergoing ADT, regarding disease-specific information, sport and physical activity, nutrition, patient advocacy groups and other information (Table 1). However, the reasons for these differences are unclear as there were no differences by centre size or geographical area.

**Table 1.** Patient information materials provided by centres and received by patients

Type of information	Centres		Patients	
	<i>n</i>	%	<i>n</i>	%
Disease-specific information	82/147	55.8*	352/509	69.2
Patient advocacy groups	98/147	66.7†	NR	
Nutrition	79/147	53.7†	146/493	29.6
Sport/physical activity	69/147	46.9†	85/491	17.3
Other	12/147	8.2†	34/441	7.7

NR, not reported.

\* Urologists were asked: In your opinion, what methods could improve patient compliance with the treatment? (multiple answers are permitted)

- More time for explanations by reducing other time-consuming obligations
- Printed material/brochures to inform patients about the disease and the benefits and possible risks of treatment
- Material on the Internet to inform patients about the disease and the benefits and possible risks of treatment
- Inclusion of family members
- Public information campaign about prostatic carcinoma and its treatment
- Greater support for patient self-help organisations
- Frequent testing of the testosterone level as an easily communicable efficacy criterion
- Frequent testing of the PSA level as an easily communicable efficacy criterion
- Patient-friendly pharmaceutical form of hormone therapy
- Other: \_\_\_\_\_

† Urologists were asked: What concomitant measures do you suggest to your patients who have prostatic carcinoma?

- Nutritional advice
- Sports groups
- Patient self-help organisations

Other: \_\_\_\_\_

Furthermore, we do not have patient-level information from centres regarding whether they provided information, only information from the patients whether they received it.

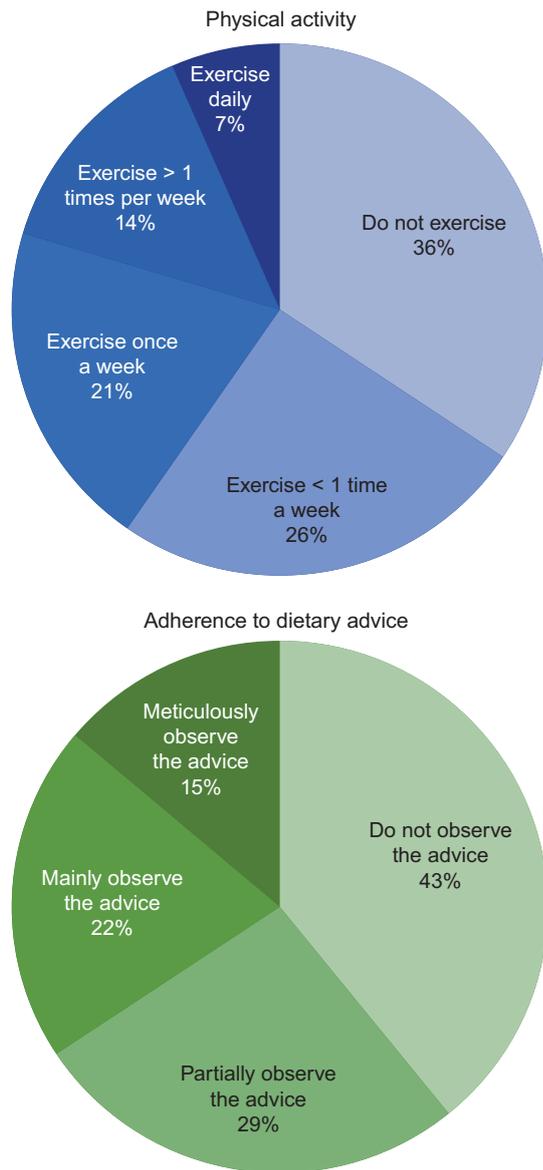
The information most provided by urologists to their patients was disease specific (83% of centres). Approximately two-thirds of participating centres (66.7%) provide information on advocacy groups to their patients. Just half of urologists reported providing information on nutrition (53.7%) and sport/physical activity (46.9%) to patients (Table 1).

Physician estimates of patients' physical activity and behavioural changes regarding diet from baseline to 1 year are presented in Fig. 1. In total, 71.4% of urologists estimated that their patients follow dietary advice only partially (28.9%) or do not follow it at all (42.5%). Similarly, 62.1% of urologists estimated that their patients rarely (26.4%) or never (35.7%) engaged in sport/physical activity.

### Patient questionnaire

In total, 69.2% of patients received disease-specific information from their urologist. By contrast, far fewer patients received information on nutrition (29.6%) or sport/physical activity (17.3%) (Table 1). In the majority of cases, additional information provided on nutrition and sport/physical activity was in the form of written material (i.e. a flyer or pamphlet). More than 80% of these patients stated that they would make use of respective information.

No evident changes were observed in the overall dietary habits of patients over the course of the study (Fig. 2). Regardless of whether they were provided information, a majority of patients did not change their dietary habits (online Supplementary Tables S1–S5). OR assessing the effect of provision of information at the



**Fig. 1.** Urologist estimates of patients' physical activity and dietary behavioural changes between baseline and 1 year (mean) (*n* 147).

start of the study are reported in Supplementary Appendix 4. For provision of information regarding eating milk and dairy approximately twice a day, the OR was 0.53 (95% CL [confidence level]: 0.29, 0.99) (online Supplementary Table S1). For provision of information regarding eating almost daily fruit and vegetables, the OR was 0.44 (95% CL: 0.20, 0.97) (online Supplementary Table S2). An OR of < 1.0 suggests that provision of information decreased the likelihood of meeting the targets. For provision of information regarding eating fish twice a week (online Supplementary Table S3), eating poultry twice a week (online Supplementary Table S4) and eating red meat three times a week (online Supplementary Table S5), the confidence interval overlapped 1.0, indicating that the results were not meaningful.

Of the 335 patients with information at baseline and after 1 year (end of study), 68.3% of patients reported no or rare sport/physical activity at baseline, with the remaining 31.6%

of patients reporting that they exercised  $\geq 1$  time per week (Fig. 3). After 1 year, the proportion of patients reporting no or rare physical activity increased to 74.3%. Similarly, the proportion of physically active patients (exercising daily or > 1 time per week) decreased from 18.8% at baseline to 16.1% after 1 year. Overall, 60.0% of patients maintained their levels of physical activity throughout the duration of the study, 17.6% of the patients increased, and 22.4% decreased their activity level after 1 year. For provision of information regarding practising sport/physical activity (online Supplementary Table S6), the confidence interval for the OR overlapped 1.0, indicating that the results were not meaningful.

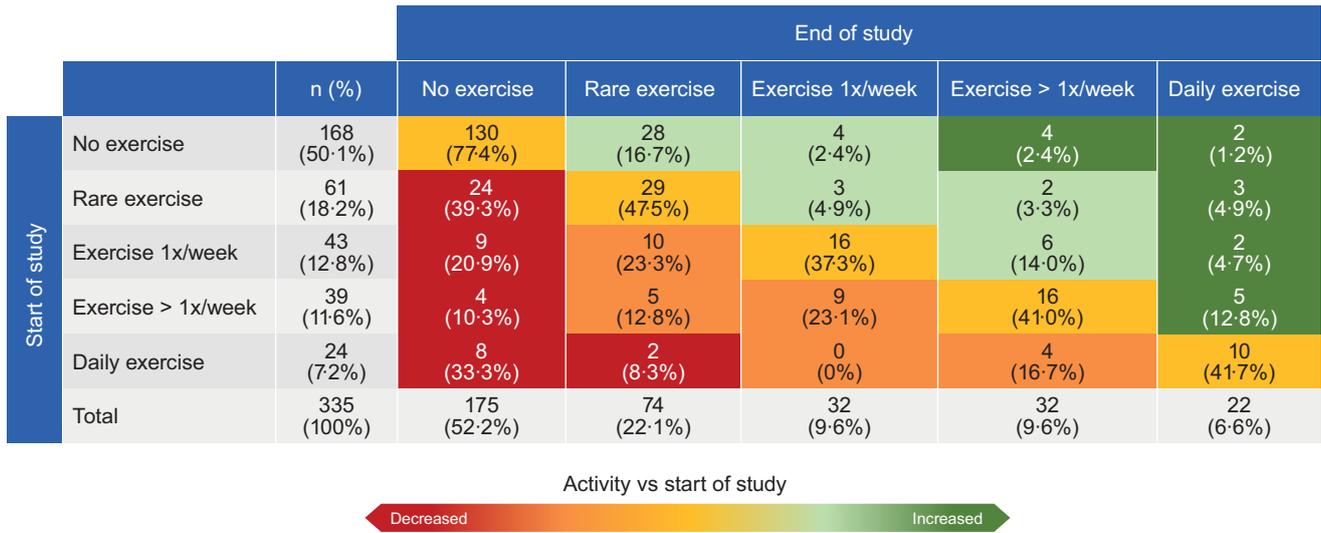
## Discussion

The present sub-analysis from the LEAN study evaluates the impact of patient information materials on the dietary and physical activity habits of PCa patients undergoing ADT, as assessed by the patient and their urologist, as well as lifestyle behavioural changes from baseline to 1 year in a real-world setting. It is apparent that while a large proportion of urologists provide disease-related materials to their patients or information on patient advocacy groups, only approximately half of urologists claim to provide their patients with information regarding nutrition and sport/physical activity (Table 1). In total, 69.2% of patients reported that they received disease-specific information from their urologist, compared with a 29.6% who received information on nutrition and 17.3% on sport/physical activity. There are several possible reasons for this: first, a lack of readily available and accepted material on nutrition and physical activity specific to PCa patients, whereas disease-specific materials and therapeutic options and flyers of local PCa patient advocacy groups are readily available in most centres. Second, urologists reported that they have little confidence that patients will comply with the recommendations on nutrition and physical activity. Finally, urologists may overestimate their activity in providing respective material as they were asked at a distinct time point. Interestingly, this contrasts with the results of the patient questionnaire, where over 90% of patients stated they would make use of this information, if provided.

This low proportion of patients receiving nutritional information corresponds with the patient self-assessment of their nutritional habits at the start and end of the study that did not support a clear change towards a healthier diet (Fig. 2). Similarly, patient physical activity had rather decreased by the end of the study (Fig. 3), possibly reflecting the low proportion of patients who received guidance on sport/physical activity. These findings appear to support the view of urologists that patients are not eating healthily or exercising regularly, while the reason for this could be explained, in part, by the discrepancy in delivery of this written information at the study centres (Fig. 1). Generally, the study was not designed to determine significance. Moreover, the CI are very wide, due to the limited patient numbers involved. As such, the weak signals that might be inferred from the dairy results, and the fruit and vegetable results (CI < 1.0) are not convincing, and providing nutrition literature to patients appears to have no meaningful effect in real-world clinical



**Fig. 2.** Nutritional changes of patients at the start and end of the study ( $n$  360). The levels were based on published nutritional guidelines (Cancer Research UK, German Nutrition Society, NHS, Prostate Cancer UK, DGA); these were not necessarily recommendations provided to the participants in the study, as this was a noninterventional, observational-only study.



**Fig. 3.** Shift table depicting patient-reported changes in physical activity over the course of the study (*n* 335).

practice. Regarding sport/physical activity, the percentage of patients improving their level of activity is higher for those provided information, but the CI is very large and the percentage who improved their level of activity is small. Generally, most patients become less active, which is unsurprising given the advancing age of the patients, disease progression, and the side effects of treatment. As with nutrition information, providing information on sport/physical activity to patients had no meaningful effect.

Several explanations are possible for the low proportion of PCa patients undergoing ADT making behavioural changes from baseline to 1 year:

(1) Patients do not receive the necessary information, or printed materials may not be enough to encourage behavioural changes.

(2) A small study by Bloom *et al.* suggests that a lack of motivation might be an obstacle<sup>(26)</sup>. Participants in this assessment felt that physicians should not only pass information but should also contribute to educating them about aspects of their disease. Limitations regarding time and expertise were recognised. O’Keefe *et al.* demonstrated that persuasiveness may play an important role in patient counselling and influence patient behavioural changes<sup>(27)</sup>.

(3) Most evidence concerning patient behavioural changes related to recommendations on nutrition and physical activity come from gynaecological studies<sup>(28,29)</sup>. It is possible that implementing behavioural changes is less likely to be successful in males than in females. Involving partners could be an important measure to improve patient behaviours regarding lifestyle recommendations.

(4) Regarding guidance on dairy and fruit and vegetable consumption, it appears that providing information may have reduced the likelihood of patients reaching nutritional targets. This may be related to patients experiencing eating problems related to cancer (e.g. nausea, vomiting, loss of appetite, sore mouth). For dairy, a further reason may be due to literature indicating that dairy consumption may be linked to prostate cancer<sup>(30)</sup>.

Although urologists in this study had doubts over patient adherence to recommendations, studies have shown that physicians can successfully influence patient behaviour change<sup>(31)</sup> and that evidence-based interventions may help patients succeed in making lasting changes<sup>(32)</sup>. However, many physicians receive little training in how to support patient behaviour change or lack confidence in providing behavioural support<sup>(31,33,34)</sup>, although training packages for healthcare professionals specifically to aid in exercise implementation in patients with PCa are being developed, for example by NICE in the UK<sup>(34)</sup>.

It is important to note that the questionnaires used in this study largely assess the use of written materials received by the patient and do not include verbal advice provided during consultations due to issues surrounding subjectivity and data collection. Written materials provide a reliable measure of patient information as it comprised the large majority of information provided to patients regarding nutrition (85.6%) and sport/physical activity (74.1%), as perceived by the patients. The findings of this study suggest that urologists and patients have different perceptions. This may, in part, be due to the different focus of the questionnaires. The urologists were questioned with respect to the common procedures followed in their centres, while answers by patients reflect their individual experiences.

Recently, the COVID-19 pandemic has had a dramatic impact on PCa patient care. Web-based technology, such as telemedicine, has increasingly been used in place of printed materials, such as flyers and leaflets. Despite the important shortcomings related to loss of direct interaction and examination, mobile phone apps and telemedicine offer advantages in terms of easier access and 24/7 availability of services related to patient education and rehabilitation. Furthermore, cancer patients often want access to a variety of information sources to reinforce the verbal information they receive, preferring written and online information, rather than written information alone<sup>(35,36)</sup>. In particular, technology-based solutions have been shown to strengthen the relationship and communication between patients and their

doctors, making patients feel more confident and empowered, supporting their active involvement in the process, and improving shared decision making<sup>(37)</sup>. A support programme for patients with PCa comprising manuals, videos, the Internet, social media and personalised consultation helped to improve information acquisition during hormone therapy and improve the self-efficacy and healthy behaviour adherence of patients<sup>(18)</sup>.

Limitations of this sub-analysis include that the urologist questionnaire was completed regarding all patients treated by the urologist, not just those receiving ADT, leuprorelin or taking part in the LEAN study. This limited assessment of the effect of providing advice on diet, exercise, etc., on patient behaviours throughout the course of the study since the questionnaire was not specific to behaviours regarding the patient population being assessed. A further confounding factor is that we cannot exclude the possibility that patients received information on diet and exercise from sources other than their treating urologist, which may have changed dietary and exercise behaviours for reasons other than advice from their healthcare professional. For example, patients may have sourced materials through a self-directed Internet search, or a partner's desire to change diet in the household could also have had an impact. We also note that, while the nutritional cut offs included in the questionnaire were based on published guidelines, the study investigators did not receive the information on nutrition and physical exercise provided from each centre, and the information provided to patients was not standardised. As such, patients receiving nutritional information did not necessarily receive the same information on nutrition that is included in the questionnaires. Thus, comparing physical activity and dietary intake to recommendations is a limitation of the study. Furthermore, the lack of validated tools to assess information provision by urologists is another study limitation.

Based on the current literature, it is reasonable to advise PCa patients who have, or who are at risk of developing, CVD to follow a nutritious diet and maintain a healthy weight. Physical activity has also been shown to be beneficial<sup>(1,2,15)</sup>. As PCa patients are likely to receive ADT for a long period of time, perhaps over a decade, and will probably receive further therapies with even greater toxicity, it is necessary to maintain their health, physical strength and good performance status. This will require complex solutions and programmes as well as continued support by patients, their partners, physicians and other healthcare providers. This observational study cannot provide the same level of detailed and comprehensive data collection found in interventional trials. Nevertheless, the data presented here provide important information on the current status of advice offered to patients undergoing ADT for PCa in a contemporary middle-European cohort. As only a limited number of patients reported receiving information on lifestyle guidance, it must be questioned whether efforts to improve survivorship efforts at centres is needed, by ensuring the delivery of behavioural information and by offering further supportive services and tools to help patients make lifestyle-based changes.

In conclusion, many patients with PCa undergoing ADT do not receive the necessary information on non-disease-related issues, such as dietary changes and physical activity. There is

a clear interest from these patients in receiving recommendations on lifestyle changes, with over 90 % claiming they would make use of this information, if provided. Yet, the majority of urologists estimate that their patients rarely or never follow this guidance. Overall, few patients made lifestyle behavioural changes, potentially due to the poor quality or quantity of relevant information or low patient motivation. It is essential to maintain the health and performance status of these patients as they will likely receive ADT for a long period of time. Complex solutions are required to maintain patient compliance over time, with the aid of a strong support network.

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All authors were responsible for drafting the manuscript and approved the final version. B. J. S. D. and B. O were responsible for conceptualisation of the study. B. J. S. D., E. B. D. G., T. E., S. M. and N. B. S. performed the patient assessments. B. J. S. D., R. S. and N. B. S performed the literature review. B. J. S. D., R. S. and B. O. analysed the data.

Bernd Schmitz-Dräger is a consultant, speaker and trialist for HEXAL AG; Ekkehardt Bismarck, Thomas Ebert and Stephan Mühlich are trialists for HEXAL AG; Bertram Ottillinger was a consultant for HEXAL AG; Peter Goebell has participated in advisory boards for and received honorary fees and travel support from Astellas, AstraZeneca, Bayer, BMS, Clinsol, Eisai, EUSA, iMedico, Ipsen, Janssen, Merck, MSD, Novartis, Pfizer, Roche and Sanofi and has received honorary fees and travel support from Apogepha; Roland Starlinger is an employee of Sandoz International GmbH and Dorothee Grammenos, Natalya Benderska-Söder and Oliver Hakenberg have nothing to declare.

### Supplementary material

For supplementary material/s referred to in this article, please visit <https://doi.org/10.1017/S0007114522003452>

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