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Brief Correspondence

Digital Therapeutics in Urology: An Innovative Approach to Patient Care and Management

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Abstract

Digital therapeutics (DTx) are a new class of intervention involving evidence-based software applications and have been used in neurology and psychiatry. To assess the potential of DTx in urology, we conducted a survey to assess the current prevalence of the digital infrastructure required for DTx, areas of support expected by patients, and requirements for uptake. Between November 2022 and January 2023, we conducted an anonymized survey at two German academic centers among patients with urologic conditions. We found that among patients aged <65 yr versus ≥65 yr, digital devices including smartphones (93.6% vs 77.3%; $p < 0.001$), computers (80.4% vs 70.1%; $p < 0.001$), tablets (51.7% vs 38.1%; $p < 0.001$), and smartwatches (24.7% vs 7.7%; $p < 0.001$) are already widely used, especially in the younger age group. Apps (95.6% vs 74.4%; $p < 0.001$) and health apps (57.6% vs 30.4%; $p < 0.001$) are already frequently used, but certified DTx apps are not (7.3% vs 5.4%; $p = 0.25$). Patients favor solutions that provide access to validated information (49.6%), give medical advice based on data or symptoms captured by the app (43.0%), or replace a physiotherapist (41.7%). Patients feel that optimization of therapy (78.4%), significant positive health outcomes (76.9%), and better patient autonomy (73.4%) are important requirements for DTx in urology. Regulatory and reimbursement changes mean that DTx might play an increasing role in urology.

Patient summary: Patients can use digital therapeutics (DTx), which are mainly smartphone apps, to improve their health status or treat medical conditions. We assessed the current and future use of DTx in urology. Patients are already widely using smartphones and frequently use uncertified health apps, but do not use DTx. Patients would like to use DTx to optimize therapy that provides a significant health improvement.

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Digital therapeutics (DTx) are a new class of intervention involving “evidence-based therapeutic interventions driven by software to prevent, manage, or treat a medical disorder or disease” [1]. As most DTx are stand-alone software solutions provided as smartphone apps, patients require a smartphone or tablet as the minimum infrastructure to access this new class of intervention [2]. Other than wellness apps, DTx are evidence-based software applications providing treatment for a defined medical indication and are regulated as medical products under medical device regulations in Europe [3].

DTx have been developed for disease areas such as neurology, psychiatry, and diabetes mellitus management. They can replace either conventional treatments such as physiotherapy and psychotherapy via video-based training, for example, or provide new types of intervention such as virtual reality-based pain treatment and acoustic treatment of tinnitus [4]. A major area is mixed applications aimed at behavioral therapy, including lifestyle changes for diabetes management, anxiety disorders, sleep disorders, drug addiction, and chronic pain. In comparison to conventional drugs, for which pharmacokinetics plays a major role, patient engagement seems to be a major factor in the success of DTx [2].

Owing to regulatory changes and new reimbursement frameworks in several European countries, starting with Germany and followed by France, the field of DTx is rapidly evolving [5]. Therefore, the Young Academic Urologists Urotechnology Group of the European Association of Urology undertook a comprehensive overview of the current treatment landscape and patient requirements. Here we report on a patient-centered survey that gives first insights into this evolving field from the perspective of a urology patient population.

We conducted a prospective patient survey to assess the current DTx landscape in urology and to analyze patients' current use, preferences, and conditions for use. The anonymized questionnaire includes six questions to capture baseline characteristics, six questions to capture current access to and use of digital technologies for health applications up to DTx, two questions on the type of support needed and requirements for use, ranked on a 5-point Likert scale, and one question to assess changes in the uptake of digital technologies as a result of the COVID-19 pandemic (Supplementary Table 1 and Supplementary Fig. 1). The survey was conducted between November 2022 and January 2023 at two German academic centers and included inpatients and outpatients with urologic conditions.

A total of 912 patients provided informed consent to participate in the study, of whom 891 (97.7%) provided complete baseline characteristics and were therefore used for further analysis. Some 735 (82.5%) patients were male and 152 (17.1%) were female. The mean age of the cohort was 61.3 yr (95% confidence interval 60.2–62.4). The leading indications for patient presentation were cancer ($n = 431$), benign prostatic hyperplasia ($n = 164$), urolithiasis ($n = 83$), incontinence ($n = 61$), and urinary tract infections ($n = 61$). Baseline characteristics revealed differences between the groups from the two centers (Table 1).

Table 1 – Patient characteristics

| Parameter | LMU Munich cohort ($n = 500$) | Uniklinik Mannheim cohort ($n = 391$) | <i>p</i> value |
|---------------------------------------|------------------------------------|--|----------------|
| Mean age, yr (95% CI) | 61.7 (60.3–63.1) | 61 (59.2–62.5) | 0.424 |
| Gender, <i>n</i> (%) | | | 0.327 |
| Male | 418 (83.6) | 317 (81.1) | |
| Female | 81 (16.3) | 71 (18.2) | |
| Gender-diverse | 1 (0.2) | 3 (0.8) | |
| Education, <i>n</i> (%) | | | 0.001 |
| No bachelor degree | 302 (60.4) | 270 (69.1) | |
| At least bachelor degree | 198 (39.6) | 111 (28.4) | |
| Condition, <i>n</i> (%) | | | 0.001 |
| Cancer | 234 (46.8) | 197 (50.3) | |
| BPH | 105 (21.0) | 59 (15.1) | |
| Incontinence | 45 (9.0) | 16 (4.1) | |
| Erectile dysfunction | 10 (2.0) | 4 (1.0) | |
| Urolithiasis | 38 (7.6) | 45 (11.5) | |
| Urinary tract infection | 43 (8.6) | 18 (4.6) | |
| Kidney failure | 7 (1.4) | 6 (1.5) | |
| Pelvis pain syndrome | 4 (0.8) | 3 (0.8) | |
| Hormonal disorder | 5 (1.0) | 1 (0.2) | |
| Infertility | 2 (0.4) | 0 (0.0) | |
| Other reason | 56 (11.2) | 68 (17.4) | |
| Unknown reason | 7 (1.4) | 14 (3.9) | |
| Urgency of presentation, <i>n</i> (%) | | | 0.002 |
| Elective | 300 (60.0) | 232 (59.3) | |
| Urgent | 136 (23.1) | 137 (35.0) | |
| Emergency | 57 (11.4) | 22 (5.6) | |
| Insurance status, <i>n</i> (%) | | | 0.007 |
| Private | 174 (34.8) | 102 (26.1) | |
| Public | 336 (67.2) | 296 (75.7) | |
| No insurance | 3 (0.6) | 0 (0.0) | |

BPH = benign prostatic hyperplasia; CI = confidence interval.

Access to digital infrastructure is a requirement for broad application of DTx. Among patients aged <65 yr versus ≥65 yr, use of smartphones (93.6% vs 77.3%; $p < 0.001$), computers (80.4% vs 70.1%; $p < 0.001$), tablets (51.7% vs 38.1%; $p < 0.001$), and smartwatches (24.7% vs 7.7%; $p < 0.001$) was higher in the younger group, while use of wearable devices did not differ between the groups (3.6% vs 2.3%; $p = 0.25$). Analysis of app use revealed higher use of apps in general (96% vs 74%; $p < 0.001$) and of health apps (57.6% vs 30.4%; $p < 0.001$) by patients aged <65 yr, and low use of certified DTx in both age groups (7.3% vs 5.4%; $p = 0.25$; Fig. 1A, B). The patients reported that the health-related apps the use are mostly fitness-related or for physician appointments (Supplementary Fig. 2).

Older patients, who theoretically need more assistance with new technologies, have less access to digital infrastructure and DTx according to our results. Therefore, clear guidance on mandatory operation manuals for DTx as medical devices, as well as accessibility aids including visual and audible support, is paramount. In Germany, these requirements are mandatory for medical devices receiving public reimbursement [6].

For future solutions regarding their current health conditions, patients favor DTx that can provide access to validate information (49.6%), give medical advice based on data or symptoms captured by the app (43.0%), replace a

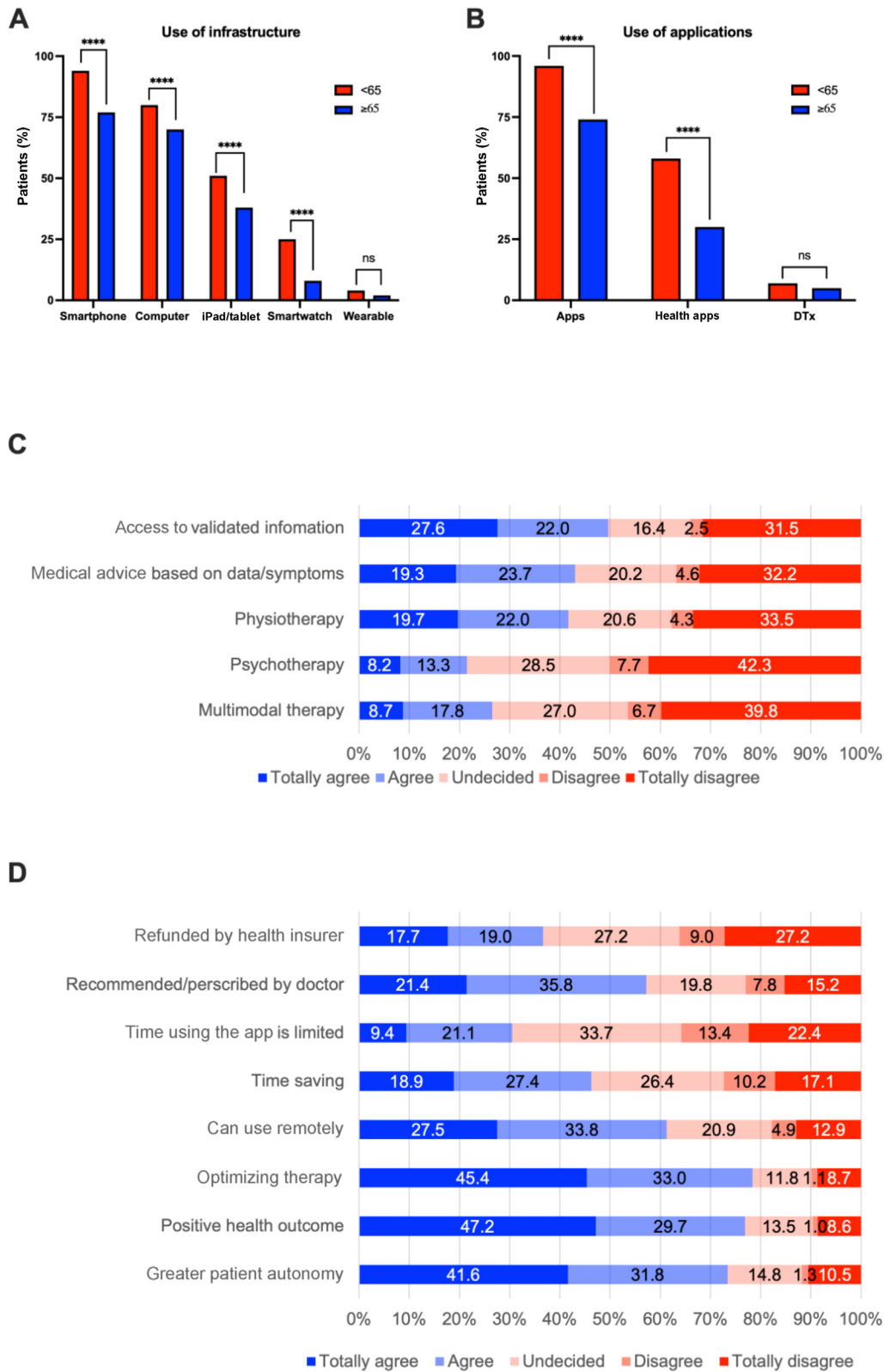


Fig. 1 – Digital infrastructure, current use, and requirements for DTx in urology. (A) Use of digital technologies for DTx application stratified by age group (<65 vs ≥65 yr). (B) Use of apps, health apps, and DTx stratified by age group. (C) Type of app preferred and (D) requirements for use assessed on a 5-point Likert scale. DTx = digital therapeutics; ns = not significant; **p < 0.001.**

physiotherapist (41.7%), replace a psychotherapist (21.5%), or deliver multimodal therapy (26.5%), with differing rates of approval across disease conditions (Fig. 1C, Supplemen-

tary Fig. 3). Factors that patients identified as requirements for DTx use are optimization of therapy (78.4%), significant positive health outcomes (76.9%), enhancement of patient

autonomy (73.4%), remote use (61.3%), prescription by a physician (57.2%), time savings (46.3%), reimbursement (36.7%), and a defined period of time for use to achieve therapy success (30.5%; Fig. 1D). Some 25.6% of the study cohort reported that they are more skilled in using technology as a result of the COVID-19 pandemic, whereas 36.1% disagreed (Supplementary Fig. 4).

Current use of DTx has been increasing in Germany since reimbursement was established [7]. Further European countries are currently follow the German lead on reimbursement. According to our survey results, a large proportion of patients have access to the infrastructure required and there is high uptake of medical apps. Therefore, evaluation of our survey across a European patient cohort will be of high interest.

The patient-urologist relationship might be impacted by DTx. The urologist prescribes DTx in the same way as for conventional drugs. However, DTx applications can generate data that can then be used to further tailor treatment decisions. Thus, valuable digital real-world data are generated, which are already being used to guide DTx reimbursement by health authorities in Germany [8].

Literature reports have revealed the feasibility of DTx for pelvic floor training, especially for the treatment of female incontinence [9]. More complex interventions for diseases such as prostate cancer are currently following, moving the field from replacement of physiotherapists to complex treatment support [10]. Patient acceptance of DTx will be of utmost importance for successful implementation of this new class of intervention in various areas of urology.

A limitation of our study is that subgroup analyses, especially regarding precise indications, were limited by the number of patients included. Furthermore, selection bias might apply, as the survey was carried out at two academic centers. To generate a comprehensive analysis of the current DTx landscape, a multicenter European study is required.

DTx are a new class of intervention that are starting to be used for patients with urologic conditions. Patients reported use of the infrastructure necessary for DTx and high engagement with health apps, but low use of certified DTx. Patients favor access to validated information and significant improvements in health outcomes as factors in their future use of DTx. Our data are encouraging for the future of DTx in urology and warrant a European multicenter study to evaluate our findings in a larger patient cohort and to elucidate the evolving role of DTx in urology across Europe.

Author contributions: Severin Rodler had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Study concept and design: Rodler, Cacciamani.

Acquisition of data: Kowalewski, Scheibert, Bensel, Stadelmeier, Styn.

Analysis and interpretation of data: Rodler, Scheibert.

Drafting of the manuscript: Rodler, Cacciamani.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.euros.2023.07.003>.

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