



Research Advances in the Application of Digital Health Care in the Care of Colorectal Cancer Stoma Patients

Zhang H and Yan Q*

Department of Nursing, Huazhong University of Science and Technology, China

*Corresponding author: Qiaoyuan Yan, Department of Nursing, Huazhong University of Science, Hubei 430022, China, Email: zhang19110420301@163.com

Review Article

Volume 7 Issue 2

Received Date: February 10, 2023

Published Date: March 07, 2023

DOI: 10.23880/nhij-16000283

Abstract

Colorectal cancer stoma patients, as a special disease population, have digital medical products applied in them in foreign countries. This paper introduces the advanced application of digital medicine in the field of colorectal cancer stoma patient care and the current situation of digital therapy development at home and abroad, analyzes and points out the challenges and development of digital medicine in the field of colorectal cancer stoma care in China and the future outlook, summarizes and points out the application prospect and development trend, aiming to promote the development of digital medicine in colorectal cancer stoma care in China to provide reference.

Keyword: Digital health; Digital therapy; Enterostomy; Care; Review literature

Abbreviations: CRC: Colorectal Cancer; WHO: World Health Organization; ED: Emergency Department; ROM: Remote Output Monitor; IARC: International Agency for Research on Cancer; ROM: Remote Output Monitor; PSM: Peristomal Skin Monitor; DTx: Digital Therapeutics; DTA: Digital Therapy Associations.

Preface

Colorectal cancer (CRC) is a major health burden worldwide. According to the Global Oncology Epidemiology Statistics released by the International Agency for Research on Cancer (IARC) of the World Health Organization, there were 1,931,600 new cases and 935,200 deaths of colorectal cancer worldwide in 2020. The third and second place of all malignant tumors, respectively [1]. Colorectal cancer ranks third in the ranking of new cancer cases and deaths by gender in the United States in 2023 [2]. Colorectal cancer is the third most common cancer by gender in the United States in 2023. Preventive colostomy rates are increasing as treatment paradigms are updated [3]. Findings indicate

that approximately 700,000 people in Europe live with a stoma, while more than 1 million in the United States have a stoma [4]. In 2020, there will be about 560,000 new cases of colorectal cancer in China [5]. The care of complications after stoma surgery is extremely important in maintaining the quality of life of stoma patients later. The incidence of stoma complications after stoma surgery has been reported to be 21%-70%, and common complications include stoma prolapse, parastomal hernia, stoma retraction, high stoma discharge and bleeding [6]. In the United States, complications from stoma surgery alone account for up to \$1 billion in medical expenditures [7]. Patients with ostomy bags are most concerned about returning to work, productivity, and concerns about their social and personal lives due to the presence of the ostomy bag [8]. Factors such as daily coping styles, acceptance and patient education by ostomy specialists have been identified as ways to improve health-related quality of life for patients with ostomy bags, but few technologies or medical devices better improve health-related quality of life for patients with ostomy bags [9,10]. The concept of rapid recovery has resulted in

shorter hospital days and increased need for post-discharge continuing care for colorectal cancer patients, and there is a lack of effective means of continuing care for patients.

Application of Digital Medicine in Colorectal Cancer Care

Digital health is the emerging field of interdisciplinary treatment of disease and health promotion through multiple digital technologies. It is defined in the Global Strategy for Digital Health published by the World Health Organization (WHO) as the field of knowledge and practice for improving health associated with the development and application of digital technologies [11]. Digital health in a broad sense includes a wide range of technologies, namely mobile health, health information technology, wearable devices, telehealth, telemedicine, and personalized medicine [11]. Digital health combines digital technology with knowledge from various disciplines such as medicine, psychology and informatics to monitor, intervene and predict patient behavior through mobile electronic devices (smartphones, bracelets, etc.) and mobile applications, etc. [12] can greatly compensate for the need for continuity of care. With the development of digital health care, a series of digital health care products have started to be put into R&D and production in the nursing field, and have achieved better expected results in foreign studies. This review addresses the application of digital health care to colorectal cancer disease.

Wearable Devices in Ostomy Products

Mobile health is an important medium for home rehabilitation as a branch of digital health, including wearable devices for health services. The earliest conception of wearable technology dates back to the 1960s and was first proposed by Edward O'Thorp [13]. In the medical field, wearable devices are used to achieve multi-parameter, real-time, online, accurate and intelligent detection and analysis of human physiological and pathological information by wearing them directly on the body, using various technical supports such as recognition, transmission sensing, cloud uploading and information storage, and can be used for self-diagnosis and self-monitoring, helping healthcare professionals to regulate, intervene and even treat patients through them [14,15].

Health and Technologies Medical has introduced a wearable colostomy device that provides assessment, reminders, health education, and can significantly reduce hospital readmissions and emergency department (ED) visits within 30 days of stoma surgery, among other features [16]. One of the main products is the wearable informational ostomy bag, which is a two-piece ostomy bag, divided into a wearable remote output monitor (ostomy bag) and a

wearable epidermal monitor (ostomy chassis). The wearable remote output monitor (ROM) this ostomy bag collects ostomy data for patients and their medical team in addition to the traditional ostomy bag function of collecting excrement. The wearable Remote Output Monitor connects wirelessly to the "11health" app, allowing patients to view their personal status, including the risk of dehydration and intestinal strictures. The healthcare team can also view patient data through the 11 health clinical interface, a remote patient monitoring platform that complies with the U.S. Health Insurance Circulation and Accountability Act. Wearable Peristomal Skin Monitor (PSM) This device distinguishes itself from traditional stoma chassis as part of a two-piece stoma care product, the Peristomal Skin Monitor (PSM) works with a Remote Output Monitor (ROM) and communicates with the "11health" app to track patient health data. Based on cloud algorithms, classification and alerts monitor patient skin health in real time. Research [6] showed that most ostomy patients experience ostomy bag leakage (defined as discharge from the stoma on the adhesive of the device and/or their clothing or bedding). Peristoma dermatitis is the most common complication of stoma complications in patients with stoma [17-19]. It is mostly caused by fecal and urine accumulation, poor sealing of the stoma sump, fecal leakage causing fecal dermatitis or neoadjuvant chemotherapy, or allergic dermatitis after contact with the skin from stoma appliances, and fecal and urine leakage is the main cause of peristoma dermatitis [19,20] and PSM can alert patients to potential peristoma skin problems and detect the risk of leakage, features that conventional ostomy bags have never had. Meanwhile Tyler, et al. [21] showed that acute hospital care use 30 d after ileostomy exceeded 38.0% (26.0% for colostomy), with a readmission rate of 24.7% and an emergency room visit rate of 17.7%. In contrast, at Robert [16]'s observational study before 30 d post-ostomy, the results showed an incidence of stoma complications of 21.2%, 15.1% of patients readmitted, and 6.1% of patients going to the emergency room for 30 days in the subject cohort using 11 Health and Technologies Medical Inc.'s product [16]. Also of particular note is that dehydration is usually the main reason for readmission after ileostomy [8]. In this study, only one patient (7%) was readmitted due to post-ostomy dehydration. The device also connects patients and health care teams to their technology-derived data, using evidence-based education and bioinformatic feedback to guide patients in promoting healthy thinking behaviors [22]. The benefits of wearable stoma products include reduced cost of care through lower resource utilisation and infection rates, reduced stoma leakage rates and reduced parastomal skin problems. The monitoring function also improves patient-provider communication, length of stay and quality of life, which not only helps improve the quality of post-operative survival for patients with stomas, but also leads to an improvement in the stigma attached to stomas in

social activities [23].

Application of 3D Printing Technology in Stoma Products

3D digital medical technology is developed on the basis of digital medical technology, which is a new modern medical approach integrating modern digital medical technology, 3D printing technology and industrial design technology. 3D printing technology can manufacture devices at once, without the combination process, the process is short, fully automatic and more efficient [24]. The traditional stoma chassis needs to be cut to the right size by nursing staff, and the common tool is the stoma caliper. However, with uncertainties such as changes in patient weight and abdominal circumference, the traditional commercial stoma chassis cannot fully adapt to the skin of the abdomen when covering the stoma, and it is easy to fall off, causing many problems of stoma excretion leakage for patients [25]. The Spanish government-funded INTELOST project, which aims to develop an ostomy bag smart chassis through 3D printing and smart technology to provide customized and personalized services based on each patient's anatomy, has been applied in the Basurto University Hospital (Spain) for general surgery, gastroenterology and urology patients at Basurto University Hospital (Spain). In other evaluations related to this device, by testing 9 cases (9/19) in which custom-made ostomy patches were applied (22 patches were delivered and tested), the results showed only 1 case of skin patch rupture and 1 case of skin irritation [25]. Meanwhile, in a study in Taiwan, China, 3D printing technology was used to create a low-cost, soft ostomy bag that fits the newborn's body and provides flexibility and comfort, while significantly reducing leakage and providing better security than the patient's own purchased ostomy bag [26]. The results show that the custom-made stoma model can be used to make a newborn stoma bag. The results show that the custom-made stoma model is effective in improving the quality of life of patients [27]. Advances in 3D printing technology allow stoma patients to address stoma incisions during both inpatient care and home self-care, helping patients and their caregivers to better replace stoma bags and reduce the impact of stoma leaks.

The advent of 3D printing technology has made it possible to reduce the manual measurement aspect of the stoma care process, reducing problems such as stoma leakage due to measurement problems. It also reduces the financial cost of stoma care for patients to a certain extent, given the financial loss of stoma pouches due to cut-out failures.

Wearable Devices in Physical Activity

In developed countries, healthcare or healthcare-related services are increasingly being provided through the use of

portable devices. The role of postoperative rehabilitation activities for colorectal cancer patients is clear, and evidence from several prospective studies strongly suggests that physical activity after colorectal cancer diagnosis reduces the risk of cancer-specific and overall mortality [28-31]. Cadmus-Bertram, et al. [32] conducted a 12-week randomized controlled trial in 50 subjects. Patients in both groups received a usual care program in the control group versus a 12-week multilevel physical activity care program in the intervention group. Results showed that 73.9% of survivors in the intervention group reported being "very satisfied" with the intervention on the satisfaction scale. Another 17.4% were "somewhat satisfied" and 8.7% were "neither satisfied nor dissatisfied". No participants were "somewhat dissatisfied" or "very dissatisfied" with the program. When asked about the importance of specific aspects of the physical activity module in helping to increase physical activity, 91.3% of participants said Fitbit was "very important" or "very important. This study determined the feasibility and short-term effectiveness of enhancing care plans through a multi-level, technology-based physical activity model for patients with breast and colorectal cancer.

In Yae Cheong [33]'s study, 102 colorectal cancer chemotherapy patients selected to receive 12 weeks of smartphone care with mobile apps and wearables, including a rehabilitation exercise program and information about their disease and treatment, showed that 75 patients completed all 12 weeks of the smartphone rehabilitation program. Patients showed significant improvements in lower extremity strength and cardiorespiratory endurance. Fatigue and nausea and vomiting symptoms were significantly reduced after the program, and patients experienced significant improvement and relief of physical performance and symptoms.

Wearable Devices in Telehealth

Remote health and safety monitoring is mainly used for the elderly, children, pregnant women and other groups. Our rapidly growing elderly population and the high associated healthcare costs have become a serious challenge. In the context of high prevalence of novel coronavirus disease, early detection and prediction of colorectal cancer and timely and accurate clinical decision making provide necessary treatment recommendations to the elderly in a timely manner. In Parvaneh Asghari [34] study, the researchers collected three types of data: personal data, clinical data and clinical IoT data through smart wearable embedded systems and medical IoT devices to provide a colorectal cancer prediction model for the participating healthcare teams through algorithms and machine learning. The experimental results show that the model can better predict the occurrence of colorectal cancer in the elderly.

Status of Digital Medical Applications

The Current Situation of Digital Medical Application in China

Digital medical products are less used in China, the development is slow, China is still in the peripheral area of digital health care, to medical platform connection is mainly dependent on medical resources, for the core area of digital therapy is in the early stage of development, into the decade China in the important areas of digital health care in the continuous construction: ① telemedicine, research shows that 53.10% of China's hospitals have carried out telemedicine services, of which remote imaging diagnosis (1) telemedicine, where studies show that 53.10% of hospitals in China have implemented telemedicine services, with remote diagnostic imaging (37.17%), followed by tele-education (32.74%); (2) mobile healthcare, where 49.56% of hospitals have implemented mobile healthcare services, mainly mobile nursing functions (36.73%) and mobile doctor check-in functions (33.63%) [35]. The development of digital therapies digital healthcare has improved access to and quality of healthcare, while to some extent easing government financial spending on healthcare. As of September 2021, more than 17 digital therapeutics (DTx) products have been approved for medical device registration in China [36]. However, currently only Zero Krypton announced that its subsidiary Zhongxi Medical Technology's digital therapeutics product TH-002 was approved for Class II medical device registration in China in the oncology care sector, the first digital therapeutics product for oncology in China [37]. In terms of medical regulation in China, in December 2017, the State Drug Administration published the Guidelines for the Technical Review of Mobile Medical Device Registration, which clearly states that all mobile medical standalone software or software+hardware used for patient management is a medical device and should be approved in accordance with the policies and processes related to medical device software in the absence of a clear regulatory process or promulgation of relevant guidelines. Meanwhile in 2021, the International Federation of Digital Therapy Associations (DTA) and Global Doctors signed a strategic cooperation agreement, in which Global Doctors will act as a strategic partner of DTA, with China as the core, to help and accelerate the comprehensive cooperation of digital therapy in China and Asia-Pacific countries, and Global Doctors is actively forming the China Digital Therapy Group.

Status of Digital Healthcare Applications in Other Countries

Currently, the development of digital health care under foreign countries has entered the core area that is digital therapy to intervene in the treatment of diseases, which

greatly reduces the dependence on medical resources. It has developed rapidly in recent years mainly for the treatment of mental health, but the treatment field is expanding to include chronic diseases such as hypertension [38] and Parkinson's [39] etc. There is also a growing number of digital therapies being used to treat mental health disorders. Digital applications of cognitive behavioral therapy are showing promising results in the treatment of depression and anxiety disorders. Digital therapies also have great potential in the field of drug development [40]. As of April 2022, the U.S. Food and Drug Administration have approved 42 digital therapy (DTx) products. In terms of healthcare regulation, the FDA identifies DTx products as mobile health applications. The FDA has released a new "Digital Health Innovation Action Plan" outlining its efforts to make its high-quality, safe and effective digital health products [40]. Providing policy support to facilitate their approval. Germany announced a digital health bill in 2019 to define digital therapies. Among other things, a digital therapy is described as a low-risk medical device that is used to diagnose, monitor, treat and/or mitigate disease or support these functions. Prior to implementation, any digital therapy app must first be listed in the German digital health app. Patients will also need to obtain a prescription for digital therapies from their physician or therapist or demonstrate their appropriate indication [41]. In Japan, a digital therapy is defined as a software program that helps diagnose, treat and prevent disease. Most DTx can be used by medical professionals or directly by patients under the supervision of a medical professional [42].

Advantages and Limitations of Digital Healthcare Development in China

Chinese colorectal cancer patients have: (1) a moderate level of post-discharge care dependency in elderly patients [43]; (2) The primary caregiver's caregiving ability is moderately low [44] (3) Uneven professional development of stoma therapists and the development of specialist nurse competency management is not yet common [45]. If digital health care is combined with nursing care to create an intelligent nursing community, reduce the number of hospital care visits for patients and provide quality and efficient medical services, thus enabling stoma patients to change the way of seeking continuous care and medical services after discharge from passive disease medical treatment to a community medical model led by prevention, health care and health education will greatly help such patients to solve their care problems, and also reduce It will also reduce the number of repeat visits for patients with stoma problems and reduce the pressure on outpatient stoma care.

However, digital health care in China is at the exploration stage with the following limitations: ① In order to understand

the advantages and limitations of its application in China, a large sample size experiment is expected to be conducted in China; ② For the rational use of digital therapy by clinical staff, no relevant clinical guidelines have been issued in China still need to be standardized training application; ③ For clinical patients, the current market price of digital medical products is high, which may lead to health care inequity [46] (iii) for clinical patients, the current high market price of digital healthcare products may lead to healthcare inequity; at the same time, digital healthcare requires the collection of many patients' information and involves patients' privacy, which makes patients need autonomy in using digital healthcare products and helps patients become participants in self-care. ④ for digital health care developers, the personal privacy aspect of patients requires industry to develop strategies to ensure data security and safe use of their products. It also provides personalized designs for different populations, such as a reasonable solution to the digital divide in elderly patients for smart devices. ⑤ For national regulators, a sound regulatory system needs to be established, product access assessment, and also a system of financial help policies for digital health care needs to be considered to give appropriate support help for product development.

Summary

Digital medicine has shown greater potential in the field of colorectal cancer stoma care, while the new crown epidemic has to some extent promoted the development of digital medicine, but how to solve the challenges in the development of digital medicine in terms of medical supervision, product efficacy verification, medical staff training system, patient acceptance of use, population habituation and other aspects of the future development is a major difficulty. The future development of digital health care in China will soon enter the digital therapy segment, which is an evidence-based intervention for diseases. The development of digital therapies has greatly promoted community-based primary care and reduced medical dependency. Ensure that digital medical products into China's health sector I think is full of potential, digital medical application development should be combined with China's national conditions, a reasonable solution to the limitations of the problem, with the continuous improvement of the economic level, promote the continuous development of technology, the popularity of residents personalized health concept, in the era of big data digital medical will play a greater role in the field of nursing, better help nursing staff to improve colorectal stoma cancer patients standard of living and quality of survival.

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