Patient navigation and cancer disparities in the era of personalized medicine

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The advent of personalized, or individualized, approaches to cancer is upon us, as robust molecular and genetic markers are identified and utilized by medical practitioners in the decision-making process. Indeed, personalized strategies are already becoming the standard of care for some cancers under certain circumstances, including colorectal cancer. Despite the increasing utility of personalized cancer care in improving outcomes and benefiting the patient community, there is a potential downside. Similar to most technical advances in health, personalized approaches may not be equally accessible across racial and ethnic groups, widening existing disparities in cancer incidence and outcomes among these groups. The time may be right to consider patient navigation, already broadly implemented in a variety of medical arenas, as a potential tool to inhibit, and indeed reverse, disparate cancer outcomes, including those related to colorectal cancer.

Power of personalized medicine

In actual fact, personalized approaches to cancer have been with us for quite some

time. Histopathological analyses have traditionally enabled classification or staging of tumors for making prognostic assessments and considering therapeutic options [1]. The more recent developments in molecular biology and genetics are rapidly changing the way we think about cancer prevention, diagnosis and treatment. It is now clear that cancer is, fundamentally, a genetic disease brought on by mutational alterations in genes that affect a myriad of biochemical pathways regulating cell growth and differentiation [2]. The number and impact of such mutations are affected by the genetic background of the individual, as well as the environment (diet and lifestyle, among others) he or she occupies. Cancer is extremely heterogeneous in terms of the particular mutated genes and misregulated pathways that underlie its emergence and progression [2]. This is why it has been so difficult to identify preventive and therapeutic agents that are effective across the spectrum of cancers, even across a single cancer type. In short, every tumor is different.

Basic research has led to the identification of those genes that have a robust

Colorectal Cancer

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role in modulating the cancer phenotype and in determining the disease's response to intervention [2]. Such genes represent potent new targets at which to direct preventive and therapeutic agents. In addition, they function as biomarkers for making a variety of predictions related to management of the disease, such as the likelihood of being diagnosed with cancer, the effectiveness of dietary and/or pharmacological interventions to prevent the disease, the probability of reoccurrence and/or progression following surgery, and the potential efficacy and toxicity of therapeutic regimens. As examples, markers that are currently in clinical use for colorectal cancer include the signaling proteins KRAS and BRAF for predicting response to therapies directed at the EGF receptor [3], microsatellite instability for identification of Lynch syndrome [4], and the Oncotype DX[®] (Genomic Health, Inc., CA, USA) colon cancer assay to assess the likelihood of cancer reoccurrence and to guide recommendations for therapy [5]. Undoubtedly, as new cancer biomarkers are identified, decision-making will become even more precise. In all, this will make the management of cancer more effective, and the outcomes significantly more predictable and favorable.

Cancer disparities among racial & ethnic groups

While overall cancer rates are declining in the USA, cancer disparities, particularly in the African-American (AA) community, persist [6,7]. Recent data indicate that during the period 2006–2010, AAs had the highest overall cancer death rate among the major racial and ethnic groups in the USA, exceeding that in European-Americans (EAs) by 11% for females and 27% for males [7]. Incidence rates in AA males are 10% higher than in EA males. The 5-year survival rates for all cancers have increased by 56% in AAs and 38% in EAs since the mid-70s; however, despite the more rapid increase in AAs, survival rates still lag behind EAs by 13% [8]. Similar disparities exist for colorectal cancer. Relative to EAs, colorectal cancer incidence is 23 and 21% higher in AA males and females, respectively; while death rates are 49 and 40% higher [8,9]. Furthermore, the declines in colorectal cancer incidence and mortality observed in the general population since 1975 have been markedly lower in AAs [8–10]. By almost any measure, AAs as a group

have suffered more from cancer, including colorectal cancer.

The causes of such disparities are multifactorial and complex, and include social dynamics (educational levels, awareness, access to medical care and insurance coverage), diet, comorbidities (obesity, diabetes and other chronic diseases) and biological factors [8–10]. Despite extensive research, cancer disparities remain a great concern to public health officials. It is pertinent to ask if the expanding use of molecular and genetic profiles as clinical tools for individualized cancer management will be effectively implemented in medically underserved communities. It can be expected that differential access to, and benefit from, personalized approaches to cancer care may widen the disparity gap, confounding attempts to eliminate it.

Patient navigation as a strategy to reduce cancer disparities

Patient navigation is an intervention provided to individual patients to reduce the barriers they may encounter in obtaining healthcare. Important to the work of navigators is the ability to communicate with and educate clients, and guide them in engaging the medical care system. In 1995, the first patient navigation program was designed and implemented in Harlem (NY, USA), by Harold Freeman in collaboration with the American Cancer Society [11]. The program was aimed at assisting medically underserved women in obtaining breast cancer screening and treatment, and was later shown to result in more effective disease diagnosis [12]. Over the last two decades, there has been an increase in the number of navigation programs across the USA, serving both insured and uninsured patients in the management of cancer, as well as other diseases. A variety of studies, only a few of which were randomized clinical trials, have evaluated the impact of navigation in breast, cervical, colorectal, head and neck, lung, and other cancers [13]. Many showed that navigation is associated with increased screening rates, earlier stage diagnosis of disease, higher levels of patient satisfaction and emotional comfort, greater awareness of clinical trials, and increased diagnostic follow-up visits [13]. In the case of colorectal cancer, significant increases in screening rates in patients receiving navigation services have been observed [13–15]. Although, in some cases, evaluations suffer from limitations, such as small sample sizes and lack of controls,

they do indicate that navigation can be highly beneficial, particularly with regard to cancer screening, and may have an important role in reducing health disparities [16].

A noted characteristic of current patient navigation programs is the heterogeneous nature of the backgrounds and training of patient navigators [13]. Indeed, social workers, nurses, lay/community volunteers and cancer survivors, among others, may function as navigators. While some formal training and credentialing programs do exist, most navigators receive a great deal of their education ‘on-the-job’, where they are given skills pertinent to the specific community they serve and the medical conditions upon which they focus.

How can patient navigation help prevent a deepening of disparities related to the implementation of personalized medicine?

As stated above, given the expansion of molecular profiling technology for individualized cancer care, there is potential for a worsening of cancer disparities, depending upon the extent to which the technology is implemented within medically underserved communities. It is worth considering the possibility that patient navigation may be a useful tool to prevent this from happening. The close one-on-one relationship between navigator and patient allows the former to educate the latter and increase his or her awareness of personalized approaches, and to understand their benefit and potential in improving health outcomes. The navigator can alleviate fears and misunderstandings, and help the patient get access to and comply with

individualized care. Overall, the navigator provides a ‘bridge’ between the molecular profiling technology and the cancer patient.

To be effective in this role, navigators will have to undergo broad-based training, in which they are exposed to the scientific, medical, public health and socioeconomic issues associated with navigation. It may be time to consider the establishment of focused educational programs within our institutions of higher learning. Interdisciplinary degree programs, located within schools of medicine, public health, professional studies or social work, may enable the kinds of indepth training needed by navigators working in a technologically fast-moving medical discipline, such as cancer. The results of such training will be navigators that understand emerging medical technologies, and their value. Furthermore, they will be able to explain the nature and utility of such technologies to patients from medically underserved populations. Finally, as needed, they will help those patients gain full access to the new technologies in order to benefit from them to the fullest extent possible.

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