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The Impact of Genetic Counseling Educational Tools on Patients' Knowledge of Molecular Testing Terminology

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Abstract

Molecular testing is increasingly being integrated into cancer management. Despite rapid advancements, little work has been done to explore strategies for communicating with patients undergoing molecular tumor testing. This study evaluated the impact of genetic counseling educational tools on improving patients' understanding of key terms related to molecular testing. A genetic counseling intern designed a picture book to explain six words found in prior research to be difficult to understand (mutation, germline mutation, somatic mutation, biomarker, molecular testing, and targeted therapy). Participants who had previously discussed molecular testing with their oncologist were asked to define the terms. The same participants then received an explanation of each term either from the intern using the picture book in person or from a video presentation of the picture book. They were then asked to redefine each term afterward. The difference between the number of terms defined correctly pre- and post-intervention was compared between presentations. Sixty-three patients with melanoma, colon, lung, or breast cancer were recruited. After both interventions, correct understanding rates improved for all six terms, with significant improvement for germline mutation ($p < 0.001$), somatic mutation ($p < 0.001$), biomarker ($p < 0.001$), and molecular testing ($p < 0.001$). Understanding of targeted therapy improved significantly ($p = 0.011$) for the video presentation only. Mean change in knowledge scores did not differ between the two interventions (intern presentation 3.2 vs. video 2.9, $p = 0.428$). Our data suggest that genetic counseling educational tools can increase patient understanding of terms used to describe molecular testing.

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Keywords

Somatic; Genetic; Genetic testing; Genetic counseling; Molecular testing; Tumor profiling; Tumor sequencing; Video

Introduction

The majority of cancers are intrinsically genetic, resulting from the accumulation of genetic changes over time. However, only about 5–10% of cancers are caused by hereditary cancer syndromes [1]. Sporadic genetic changes account for the vast majority of cancer occurrences in the population regardless of age [2]. Additionally, since knowledge regarding the relationship between genetics and tumorigenesis has increased quickly over the past 20 years [3, 4], there has been a rapid expansion in the use of molecular testing to guide patient care.

Mutations found through molecular testing are currently being used for classification, therapeutic management, prognostication, predicting treatment sensitivities, and monitoring treatment response for numerous types of cancer [5]. Specifically, in non-small cell lung cancer (NSCLC), tumor profiling is being used to guide treatment by identifying patients with targetable driver mutations in genes like *ALK* and *ROS1* [6]. Additionally, *RAS* genotyping has been used extensively in the colorectal cancer patient population to predict susceptibility to EGFR inhibition therapies [7]. In the treatment of metastatic melanoma, targeted therapies have been shown to improve progression-free survival in patients with BRAF V600E driver mutations [8]. Furthermore, biomarker-driven approaches like the multigene Oncotype DX® assay and receptor-based targeted therapies have been used extensively to personalize the management of patients with breast cancer [9, 10].

Although molecular testing has paved the way for personalized treatment in clinical oncology, genomic approaches have also increased the complexity of communicating with patients. Several studies have identified gaps in provider communication with patients regarding genomic approaches to treatment [11, 12]. Specifically, one study demonstrated that patients with cancer tend to overestimate the relative contribution of inherited genetic changes to cancer diagnoses and underestimate the complexity of cancer genetics [13]. In a preliminary study, we found that four terms—'mutation,' 'biomarker,' 'molecular testing,' and 'targeted therapy'—were frequently misunderstood by patients (between 40% and 63% of the time), even after molecular testing conversations with their oncologists. We also found that the patients did not understand the difference between somatic and germline mutations (Pocock et al., unpublished data). Not only does this lack of understanding jeopardize patients' ability to give informed consent, but low comprehension has also been associated with poor adherence to treatment and suboptimal health outcomes [14].

Despite these documented knowledge gaps, minimal work has been done to improve communication strategies within this population. In contrast, genetic counseling educational tools have repeatedly been shown to increase knowledge and improve health outcomes in the context of hereditary cancer [15]. Many hereditary cancer counselors see oncology patients whose tumor profiling results are suggestive of a germline mutation. However, providing genetic counseling prior to tumor profiling would be infeasible given the current shortage of

genetic health professionals [16]. Thus, it has been suggested that educational videos covering genetic counseling topics may provide a mechanism to fill this informational need [17].

Educational videos have been used in numerous oncology settings and have already been shown to improve knowledge in the setting of hereditary cancer [17–20]. Thus, the current study tested two communication methods: a genetic counseling intern presenting a picture book on molecular testing terms in-person to patients and the same picture book converted to a stand-alone video tool. Our goal was to see if each method improved patients' understanding of molecular testing. We hypothesized that the picture book would increase patient understanding both when explained by a genetic counseling intern and when converted to a stand-alone video format.

Methods

Participants

This study was approved by the institution's Institutional Review Board. Oncologists from our previous study were asked to work collaboratively with a genetic counseling intern and a research assistant (RA) to identify their eligible patients each day. Eligible patients included English-speaking adults who (1) had lung cancer or melanoma and had discussed TruSight Tumor 26 (Illumina, San Diego, CA) molecular testing with their oncologist; (2) had colon cancer and had discussed Foundation One (Foundation Medicine, Cambridge, Massachusetts) molecular testing with their oncologist; or (3) had breast cancer and had discussed either Oncotype DX® (Genomic Health, Redwood City, CA) molecular testing or receptor targeted therapies with their oncologist. Patients with other primaries outside of lung, melanoma, colon, and breast were excluded from the study. Eight patients were recruited in the oncology consult rooms after their molecular testing conversation with their oncologist, while the remaining 55 patients were recruited in the infusion center at an academic cancer center. A written informed consent was obtained from each patient prior to entering the study.

Instrument Design

The genetic counseling intern's advisory panel determined that the six terms found to be misunderstood in our previous study would be appropriate to use in this pilot test. Thus, the picture book was designed to illustrate the following six terms: 'mutation,' 'germline mutation,' 'somatic mutation,' 'biomarker,' 'targeted therapy,' and 'molecular testing.' The original picture book was reviewed by a molecular pathologist, a genetic counselor, and a bioethicist. The revised picture book was cognitively tested with eight patients (two patients each with lung cancer, colon cancer, breast cancer, or melanoma) using the think-aloud method [21]. The patients were shown the images in the picture book and asked to communicate their impression of the meaning of the pictures. They were also asked to inform the investigators of any pictures they found to be confusing. Patient feedback was incorporated into the final version of the picture book. The picture book was then converted into a video presentation using Microsoft PowerPoint and the genetic counseling intern recorded a voiceover to accompany the images.

Procedures

The genetic counseling intern or RA asked each participant to answer 14 demographic questions. We then used the Kilbridge method to determine the participants' understanding of the six terms, which was previously used successfully in another cancer setting [22–24]. The intern or RA asked the participant whether or not he/she understood each term. If the participant answered "yes", he/she was asked to define the term in his/her own words. The intern or RA wrote down the definitions verbatim. If the participant answered "no", the intern or RA moved on to the next term. For the in-person approach, the intern used the picture book to explain each word to the participant and answered all participant questions. For the video approach, the RA showed the video presentation, but did not answer questions. Participants were recruited sequentially; with the first cohort receiving the in-person approach, and the second cohort receiving the video presentation. Immediately following each intervention, the participant was asked to re-define the words to assess changes in comprehension. Following the assessment of understanding, each participant was asked to rank the extent to which he/she agreed with the following statements: "I understand what was explained to me about tumor genomic profiling" and "I am satisfied with what was explained to me about tumor genomic profiling."

Statistical Analysis

To compare the participant's understanding of the six genomic words before and after the interventions, all participant definitions were coded as correct or incorrect by two independent coders until consensus was reached for all definitions. Responses were coded as correct or incorrect based on the degree of similarity to the standard definition provided in the picture book and video presentation. Responses were coded as incorrect either if the participant answered "no" when asked if they understood a particular term or if they defined a term incorrectly. The proportion of correct responses for each word before and after each intervention was compared using McNemar's tests. The knowledge score for each participant before and after each intervention was calculated by summing his/her number of correct definitions. Knowledge scores ranged from zero to six potential points. The mean knowledge score before the intervention was compared to the mean knowledge score after the intervention using a paired t test. Mean change in knowledge scores (post minus pre) was compared between intervention types using a two-sample t test. Levels of perceived patient understanding and satisfaction were summarized using frequency counts.

Demographic characteristics were summarized using frequency counts and percentages. Secondary analyses were done to assess whether certain demographic characteristics were related to changes in knowledge scores. Due to our small sample size, certain demographic characteristics were compressed into either dichotomous or trichotomous outcomes. Kruskal-Wallis tests were used to assess the effect of cancer type, gender, ethnicity, education level, income, having work experience in healthcare, having a family member with work experience in healthcare, and having a family member with cancer on changes in knowledge, with pairwise comparisons handled using the Dwass, Steel, Critchlow-Fligner (DSCF) approach for variables with three or more levels. Spearman's correlation coefficient was used to assess whether there was a significant relationship between age and changes in knowledge. For each intervention type, the proportions of correct responses for mutation and

targeted therapy prior to intervention were compared across demographic characteristics using chi-squared tests, Fisher's exact tests, or Kruskal-Wallis tests where appropriate. Demographic characteristics were compared across intervention types using chi-squared tests or Fisher's exact tests, where appropriate for categorical variables, and using two-sample *t* tests for numeric variables. All statistical analyses were performed using IBM SPSS Statistics Software (Version 25) or SAS 9.4 (SAS Institute Inc., Cary, NC), and statistical significance was assessed at the 0.05 level. All statistical tests were two-sided, where appropriate.

Results

Participants

Thirty-four participants were offered the intern presentation and 42 participants were offered the video presentation for a total of 76. Ten patients declined participation (6 in the in-person cohort and 4 in the video presentation cohort). Three additional patients could not complete the video (one could not hear and was declared ineligible, for another the video malfunctioned and the last participant became distracted and could not complete the study). The final total was 63 participants, with an 83% response rate. Reasons for declining included feeling sick, tired, overwhelmed, lacking interest, and not having enough time. Demographics of participants are described in Table 1. Non-white participants included 10 Black/African American participants, 6 Asian or Pacific Islander participants, 2 Hispanic/Latino participants, and 2 mixed race participants. The only significant difference among the two intervention arms was that the intern presentation had a significantly higher number of breast cancer patients (57% vs. 31%, $p = 0.04$), and as a result a higher number of women (75% vs. 49%, $p = 0.03$), compared to the participants given the video presentation. The higher number of breast cancer patients in the intern presentation arm was due to our convenience sampling and was reflective of a difference in physician referral patterns during the accrual of the two cohorts.

Patients' Understanding of Six Molecular Testing Words

Comparisons of correct understanding rates for each word before and after the two interventions are presented in Table 2. Both approaches improved understanding rates for all six terms. Understanding rates were significantly improved ($p < 0.001$) after both the intern and video presentations for the terms 'germline mutation,' 'somatic mutation,' 'biomarker,' and 'molecular testing.' Additionally, the understanding rate for 'targeted therapy' significantly improved ($p = 0.011$) following the video presentation only. None of the demographic characteristics we assessed were related to pre-test knowledge of the term 'targeted therapy.' However, pre-test knowledge of the term 'mutation' was significantly related to education level in the video presentation ($p = 0.028$) and both ethnicity ($p = 0.020$) and work experience in healthcare ($p = 0.030$) in the intern presentation group.

Knowledge Scores

For both intervention groups, pre-test total knowledge scores—the number of words correctly defined out of the six words—ranged from zero correct definitions to four correct definitions. The pretest mean total knowledge score for the participants prior to the intern

presentation was 1.8 words correct out of 6, which equates to an overall knowledge score of 30%. The mean pre-test knowledge score for the participants shown the video presentation was 1.3 words correct, which equates to an overall knowledge score of 21.8%. After both interventions, post-test knowledge scores ranged from zero words correct to six words correct. After the intern presentation, the mean knowledge score significantly improved from 1.8 out of 6 (30%) to 5 out of 6 (83.3%) ($p < 0.001$). For the video presentation, the mean knowledge score significantly improved from 1.3 out of 6 (21.8%) to 4.2 out of 6 (70%) ($p < 0.001$). The mean change in knowledge scores did not significantly differ between the two interventions ($p = 0.428$) (Table 3).

Education level was significantly related to changes in knowledge for both the intern presentation ($p = 0.030$) and the video presentation ($p = 0.006$). In the video presentation group, participants with a high school or associate's degree had significantly lower changes in knowledge (mean 1.55) compared to participants who had an undergraduate (mean 3.78) or graduate degree (mean 3.33). In the intern presentation group, participants with an undergraduate degree had a significantly higher change in knowledge score (mean 3.86) compared to those with a graduate degree (mean 2.58); however, those with a high school or associate's degree did not have a significantly different change in knowledge (mean 3.38) compared to those with either an undergraduate or graduate degree. Cancer type, gender, age, ethnicity, income, having work experience in healthcare, having a family member with work experience in healthcare, or having a family member with cancer were not related to changes in knowledge.

Perceived Participant Understanding

The majority of the participants in each group reported they completely understood the intern's explanation or the explanation given in the video. A higher percentage of participants reported that they completely understood the intern's explanation (75%) compared to the video explanation (65.7%), but the difference was not significant. Additionally, 21.4% of the participants reported that they partially understood the intern's explanation while 28.6% of the participants reported that they partially understood the video explanation. No participants indicated that they did not understand the video or intern's explanation.

Perceived Participant Satisfaction with Genetic Counseling

A higher percentage of participants reported complete satisfaction in response to the intern's explanation (89.2%) compared to the video explanation (74.3%), but the difference was not significant. 7.1% and 3.6% of participants given the intern presentation reported partial and neutral levels of satisfaction, respectively. Additionally, 20% and 2.9% of participants given the video presentation reported partial levels of satisfaction and neutral levels of satisfaction, respectively. One participant reported being partially dissatisfied with the explanation given in the video presentation. None of the participants in either group reported complete dissatisfaction.

Discussion

This is the first study to explore the benefit of using genetic counseling educational tools to increase patients' understanding of molecular testing terminology. Correct understanding rates improved for all six terms following both approaches, with significant improvement for four out of six words following the genetic counseling intern's in-person explanation and for five of six words following the video presentation. The lack of significant improvement for the terms 'mutation' and 'targeted therapy' following the intern presentation can likely be explained by the high initial participant understanding rates of 75% and 71.4%, respectively, and our relatively small sample size. Similar explanations can be applied to the lack of significant improvement for the term 'mutation' following the video presentation, which had a high pre-intervention understanding rate of 75%.

The understanding rates for 'mutation' and 'targeted therapy' were also higher than they were in our previous study, in which the understanding rates were 51% for mutation and 59% for targeted therapy (Pocock et al., unpublished). Larger studies are warranted to determine if our inability to detect a significant improvement for these words can be accounted for by our small sample size and our study's demographic characteristics. However, it is also possible that these terms may not need to be explained in an educational tool given such high initial patient understanding rates.

Mean knowledge scores significantly improved from 1.8 (30%) to 5.0 (83.3%) after the intern presentation and from 1.3(21.8%) to 4.2 (70%) after the video presentation. Additionally, the video presentation did not significantly differ from the intern presentation in mean change in knowledge score (5.0 vs. 4.2, $p = 0.428$). These findings indicate that the video presentation improved patient understanding to a similar extent as the presentation from the genetic counseling intern. Thus, we have demonstrated that the use of genetic counseling educational tools in this setting can substantially improve patient understanding. This finding is consistent with previous literature regarding the benefit of using similar tools in the context of hereditary cancer syndromes [25]. Furthermore, the majority of the patients reported complete understanding and complete satisfaction with the intern's presentation of the picture book and with the video presentation.

Although our study has many strengths, we also recognized that our study is limited by our small sample size of 63 patients and our convenience sampling approach. We asked the oncologists to identify their eligible patients each day. However, we realize that the selected patients may not be representative of all patients undergoing molecular testing. Specifically, our study population was highly educated, with over 40% having graduate-level degrees in both intervention populations. This demographic bias is important to highlight since education level was significantly related to changes in knowledge in our sample. Our small sample size may also account for the dissimilarities between intervention arms in how change in knowledge scores significantly differed based on educational levels. Modifying the picture book or video presentation towards a wider range of educational levels should be explored in the future.

This study was also limited by being conducted at a single academic cancer center, and we recognize that our tool may not be equally effective in non-academic healthcare settings. Another weakness that we recognize is that when using the Kilbridge method to determine patient understanding, we are limited in our ability to distinguish between patient recall and full comprehension of the assessed terms. Finally, data on the frequency of each term's usage during the patients' conversations with their oncologists was not collected. Thus, it is not clear whether the initial patient understanding rates reflect gaps in provider communication and patient understanding, or a lack of provider word usage among the patients in this study.

In conclusion, this study shows that genetic counseling educational tools can improve patient understanding of key terms related to molecular testing. A picture book presented by a genetic counseling intern in-person and the picture book converted to a stand-alone video tool were similarly effective in improving understanding. Greater understanding of these terms as a result of these educational tools has the potential to improve the process of informed consent and reduce the potential for inaccurate patient interpretations in this setting. Thus, the use of similar educational tools should be further explored in larger studies.

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Table 1

Demographic Characteristics

Characteristic	Intern (*N* = 28) Frequency *n* (%)	Video (*N* =35) Frequency *n* (%)	Total (*N* = 63) Frequency *n* (%)
Cancer type			
Breast	16 (57.1)	11 (31.4)	27 (42.9)
Colon	6 (21.4)	10 (28.6)	16 (25.4)
Melanoma	4 (14.3)	11 (31.4)	15 (23.8)
Lung	2 (7.1)	3 (8.6)	5 (7.9)
Gender			
Male	7 (25)	18 (51.4)	25 (39.7)
Female	21 (75)	17 (48.6)	38 (60.3)
Age			
Mean (range)	52.9 (31–84)	54.8 (21–80)	54.0 (21–84)
Ethnicity			
White/Caucasian	19 (67.9)	24 (68.6)	43 (68.3)
Other	9 (32.1)	11 (31.4)	20 (31.7)
Education level			
HS or associate’s degree	7 (25.9)	11 (31.4)	18 (28.6)
Bachelor’s degree	7 (25.9)	9 (25.7)	16 (25.4)
Graduate degree	13 (46.4)	15 (42.9)	28 (44.4)
Refused	1 (3.6)	0 (0.0)	1 (1.6)
Annual income			
< 50,000	7 (25.0)	10 (28.6)	17 (27.0)
50,000–99,999	7 (25.0)	3 (8.6)	10 (15.9)
>100,000	7 (25.0)	18 (51.4)	25 (39.7)
Refused	7 (25.0)	4 (11.4)	11 (17.5)
Work experience in healthcare			
Yes	10 (35.7)	8 (22.9)	18 (28.6)
No	18 (64.3)	27 (77.1)	45 (71.4)
Family member with work experience in healthcare			
Yes	11 (39.3)	11 (31.4)	22 (34.9)

Characteristic	Intern (*N* = 28) Frequency *n* (%)	Video (*N* =35) Frequency *n* (%)	Total (*N* = 63) Frequency *n* (%)
No	17 (60.7)	24 (68.6)	41 (65.1)
Family member with cancer			
Yes	18 (64.3)	19 (54.3)	37 (58.7)
No	10 (35.7)	16 (45.7)	26 (41.3)

Table 2

Correct understanding rates for each term before and after intern presentation ($N = 28$) or video presentation ($N = 35$)

Genomic word	Correct before intern *n* (%)	Correct after intern *n* (%)	*p* value[a]	Correct before video *n* (%)	Correct after video *n* (%)	p value[a]
Mutation	21 (75)	22 (78.6)	1.00	22 (62.9)	27 (77.1)	0.059
Germline mutation	0 (0)	25 (89.3)	<0.001	1 (2.9)	26 (74.3)	<0.001
Somatic mutation	0 (0)	27 (96.4%)	<0.001	1 (2.9)	27 (77.1)	<0.001
Biomarker	7 (25)	22 (78.6)	<0.001	3 (8.6)	22 (62.9)	<0.001
Molecular testing	3 (10.7)	20 (71.4)	<0.001	3 (8.6)	21 (60)	<0.001
Targeted therapy	20 (71.4)	24 (85.7)	0.344	16 (45.7)	24 (68.6)	0.011

[a]McNemar's test comparison of the proportion of correct versus incorrect definitions before and after the genetic counseling interventions

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Table 3

Total knowledge scores pre- and post-intervention

Total knowledge score[a]	**Picture book (*N* = 28)**	**Video (*N* = 35)**	***p* value**[b]
Pre-intervention mean (%)	1.80 (30)	1.31 (21.8)	
Post-intervention mean (%)	5.00 (83.3)	4.20 (70)	
Change in score (%)	2.89 (53.3)	3.18 (48.2)	0.428

[a]Total knowledge scores ranged from 0 to 6 potential words correct

[b]The p value was evaluated using a two-sample t test