Objective: The aim of this study was to analyze the psychometric properties of the Shared Decision-Making Questionnaire-Physician version (SDM-Q-Doc) in a sample of medical oncologists who provide adjuvant treatment to patients with non-metastatic resected-cancer and the correlations between the total SMD-Q-Doc score and physician satisfaction with the information provided.

Methods: Prospective, observational and multicenter study in which 32 medical oncologists and 520 patients were recruited. The psychometric properties,
dimensionality, and factor structure of the SDM-Q-Doc were assessed. Results: Exploratory factor analyses suggested that the most likely solution was two-dimensional, with two correlated factors: one factor regarding information and another one about treatment. Confirmatory factor analysis based on cross-validation showed that the fitted two-dimensional solution provided the best fit to the data. Reliability analyses revealed good accuracy for the derived scores, both total and sub-scale, with estimates ranging from 0.81 to 0.89. The results revealed significant correlations between the total SMD-Q-Doc score and physician satisfaction with the information provided (p<0.01); between information sub-scale scores (factor 1) and satisfaction (p<0.01), and between treatment sub-scale scores (factor 2) and satisfaction (p<0.01). Medical oncologists of older age and those with more years of experience showed more interest in the patient preferences (p= 0.026 and p= 0.020, respectively). Patient age negatively correlated with SDM-information (p<0.01) and physicians appear to provide more information to young patients. Conclusion: SDM-Q-Doc showed good psychometric properties and could be a helpful tool that examine physician's perspective of SDM and as an indicator of quality and satisfaction in patients with cancer.

### Additional Information:

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Title:
Validation of SDM-Q-Doc Questionnaire to measure share decision-making physician’s perspective in oncology practice.

Running Head:
Shared Decision Making- Physician’s perspective in oncology.

Authors:
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ABSTRACT

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Conclusion: SDM-Q-Doc showed good psychometric properties and could be a helpful tool that examine physician’s perspective of SDM and as an indicator of quality and satisfaction in patients with cancer.

Keywords: cancer; medical oncologist; physician’s perspective; psychometrics properties; shared decision making.
Introduction

Improved diagnostic and screening techniques enable ever more cancers to be detected in localized stages [1]. Systemic adjuvant treatments are being used with growing frequency and effectiveness following surgery on these early tumors to reduce relapse and mortality rates [2,3]. However, the increasing complexity of these treatments and their administration to vulnerable people have had a negative impact on patient quality of life, due to adverse effect.

In response to this growing complexity surrounding decision making, new clinical practice models have arisen in recent decades, such as the biopsychosocial [4,5] and patient-or relationship-centered models [6,7]. While all coincide in that the disease in its biological sense is the most important therapeutic target, they also seek to incorporate patients’ perspectives, concerns, and preferences so as to interact on an emotional level and take them into account when deciding on the treatment plan.

Moreover, the initial interview with a medical oncologist to talk about the risk and benefit of adjuvant chemotherapy following a surgery with curative intent has its own idiosyncrasy. This peculiarity is due to the probabilistic element of the need for treatment and the risk of recurrence; to the duality of a technical, yet emotional interaction and to the regular order of events that situates this interview after surgery, which means that the diagnosis and bad news will have already been communicated. After discussing the advantages and disadvantages, individualized, consensual shared decision-making (SDM) ensues.

Recent years have witnessed the evolution of decision-making tools to aid in treatment selection, providing quantitative estimations of the risks and benefits of clinical guideline recommendations [8]. Gaining insight into the physicians’ points of view of this new way of making oncological decisions is one way to enrich the process and for more patients to benefit from curative cancer treatments and share in the decision.

The SDM-Questionnaire-physician version (SDM-Q-Doc) was elaborated to evaluate physicians’ perspectives about these decision-making processes [9]. However, the psychometric properties and potential usefulness of this instrument in the clinical context of adjuvant cancer therapy have remained unexplored. The aim of this study was to assess the psychometric properties of the SDM-Q-Doc version in a sample of medical oncologists who provide adjuvant treatment to patients with non-metastatic resected-cancer and the correlations between the total SMD-Q-Doc score and physician satisfaction with the information provided.

Methods

Participants
The sample consists of patients undergoing curative surgery for non-metastatic cancer and recruited from June 2015 to November 2016. Data were collected in a cross-sectional, prospective, observational study that was part of a research program on patients with cancer funded by the Continuous Care Group of the Spanish Society of Medical Oncology (SEOM). The study was approved by the Ethics Review Board at each institution in accordance with the 1974 Declaration of Helsinki revised in Seoul in 2008 and by the Spanish Agency of Medicines and Medical Devices (AEMPS). Data collection procedures were similar for all hospitals. Participation was voluntary, anonymous, and would not affect patient care. The participants completed the questionnaires individually, with no limit on time, and special attention was paid to ensure data privacy and confidentiality. Variables were collected via a centralized website (www.neocoping.es).

**Instruments and adaptation**

SDM-Q-Doc. The SDM-Q-Doc is a questionnaire that assesses the physician’s perspective [9]. The questionnaire consists of nine items, each of which describes one step in the process; for instance, ‘My patient and I thoroughly weighed the different treatment options’. The items are scored from 0 to 5 on a six-point Likert scale ranging from “completely disagree” (0) to “completely agree” (5). A total raw score of between 0 and 45 is calculated by adding the scores of all items. The German version of the SDM-Q-Doc was reported to have good reliability ($\alpha = 0.88$) [9].

SMD-Q-Doc adaptation. The aim of the adaptation process was to keep the wording of the Spanish version as similar as possible to the original (SDM-Q-Doc), minimizing differences between both versions in item interpretation. We used the guidelines described for the process of cross-cultural adaptation of self-reported measures [10]. Specifically, for the translation, two independent bilingual translators, competent in both English and Spanish, translated the original questionnaire from English into Spanish. Translators reached consensus on the translation of words, phrases and items based on the synthesis of the translations, working from the original questionnaire as well as the first translator’s and the second translator’s versions. For cultural appropriateness and content validity, four independent physicians and psychologist performed testing. They rated understandability, translation equivalences and content validity. Another two bilingual translators who were blind to the original English version back translated the revised Spanish version, and finally, the study directors compared and synthesized the back-translation with original questionnaire, culminating in a final version. The final version was pre-tested with the first thirty-four adult patients attended who were invited to participate in this study. Their responses were analyzed to identify necessary modifications; however, it was not necessary to make any modification after this pre-test.
Physician satisfaction with the information provided. A 5-item scale was created to ascertain physicians' degree of satisfaction with the information provided about the disease, risk of recurrence, side effects of treatment, and time dedicated to informing the patient. The items were scored from 0 to 10; the higher the score, the greater the physician's satisfaction with the information provided.

Demographic data. The following data were obtained with respect to patients' medical and demographic characteristics: gender, age, marital status, educational level, occupational field, tumor site, stage, and time since diagnosis. The oncologist-related variables included age, years of experience, and area of specialization: general (treating all kinds of tumors) and super-specialized (treating one specific subtype of tumor).

Statistical analyses
The data analysis process can be summarized in 4 stages: (a) descriptive analyses, (b) dimensionality and structure assessment (i.e., item calibration), (c) scoring and reliability assessment, and (d) validity determination. Descriptive analyses were first conducted for each SDM-Q-Doc item score and the adequacy of the inter-item correlation matrix to be factor analyzed was examined using the Kaiser-Meyer-Olkin (KMO) index. Next, to gauge the scale's dimensionality and factor structure, and minimize capitalization on chance, the sample was randomly split into two sub-samples. First, Exploratory Factor Analysis (EFA) solutions were fitted on the first subsample by using robust, unweighted least squares estimation with mean-corrected fit statistics as implemented in the FACTOR program [11]. Considering that the original scale displayed a one-dimensional structure [9], we started by testing the uni-dimensional solution.

Given that the EFA provided a clearly interpretable solution that approached simple structure, a confirmatory factor analysis (CFA) solution was next fitted to the entire sample using robust, weighted least squares estimation with mean-and-variance corrected fit statistics as implemented in the Mplus version 5.1 program [12]. In both EFA and CFA solutions, the goodness-of-fit indices used to appraise model appropriateness were: (a) Root Mean Square Error of Approximation (RMSEA), with its 90% confidence interval as a measure of approximate fit; (b) Goodness-of-fit index (GFI); (c) the root mean square of the standardized residuals (z-RMSR), as absolute measures of fit, and (d) the comparative fit index (CFI), as a relative measure of fit with respect to the null independence model. We followed the usual rules in deciding model appropriateness [13]. Once the SDM dimensionality and structure had been established, scores based on the solution adopted were obtained. We contemplated two types of scoring schemata: EAP factor scores derived from the factorial solution and the usual raw scores attained as the simple sums of the scores on the items that define the corresponding factor. Reliability was estimated
for both types of scores, and, in the case of raw scores, the omega reliability estimate was chosen [14].

Finally, as to validity, product-moment correlations were used to quantify the relation between SMD-based scores and physician satisfaction with the information provided and patient and physician characteristics. For this validity analysis, we used the IBM-SPSS 23.0 statistical software package (SPSS, INC., Chicago, Ill) for Windows PC.

Results

Sample characteristics

Thirty-two medical oncologists from 14 Spanish hospitals participated in this study; 78.1% (n= 25) were females; mean age was 35 years (SD= 7.2, range 27-58), and 11.9 years of experience (SD= 8.8, range 3-37). No significant differences were found between male and female oncologists with respect to age (t= 0.308, p= 0.760) or years of experience (t= -1.348, p= 0.470). Most were super-specialists (68.8%) and worked at a public, teaching hospital (53.1%) (see Table 1).

These medical oncologists recruited 562 patients, of whom 42 were excluded from the study (14 because they failed to meet the inclusion criteria; 15 met an exclusion criterion, and 13 had incomplete data). Figure 1 outlines the recruitment process. The final patient sample consisted of 520 individuals; 67.1% (n= 313) were female, with a mean age of 59.2 years (SD= 12.2, range 26-85). Most were married or partnered (77%) and had a primary level of education (69.5%). The most common employment status was retired (64.6%). As regards the sample’s clinical characteristics, the most frequent kinds of cancer were colon (40.4%); breast (35.2%) and stomach (6.7%). Everyone received adjuvant chemotherapy and 36.6% received associated radiotherapy.

Descriptive analyses

The mean sum score of SMD-Q-Doc was 4.53 (SD= 0.56). The highest score was found on item 5, “I helped my patient understand all the information” mean score (4.80); whereas item 6, “I asked my patient which treatment option he/she prefers” scored lowest mean (4.24). No significant differences were found for clinical oncologists’ specialization, type of hospital, number of years employed, or gender.

In general, item scores were distributed asymmetrically (negatively skewed) and some had skewness coefficients an absolute value of greater than one. Furthermore, given that the test is not very long and the sample is reasonably large, we considered that the best choice was to use the underlying-variables approach, and fit the FA models (both exploratory and confirmatory) to the inter-item polychoric correlation matrix [15]. Finally, results from the KMO index (0.872) and Bartlett’s test (χ²= 2307.9, df= 36, p< 0.001)
suggested that the inter-item relations were consistent enough to be fitted by the FA model.

**Exploratory factor analyses**

The uni-dimensional solution does not achieve an acceptable fit according to all the standards (RMSEA and z-RMSR are too high), whereas the two-factor solution fit can be deemed acceptable. Given the reduced number of items and small residual values after extracting two factors, no models with a higher number of dimensions were tried.

The Oblimin rotated two-factor solution revealed a clear structure that was easily interpretable (see table 2). Factor I, clustered items 1, 2, 3, 4, and 5, all of which assess the information and explanations the physician gives the patient regarding treatment and the advantages and disadvantages of the different treatment options. Factor II was defined by items 6, 7, 8, and 9, all of which examine the choice of the best treatment option for the patient. The rotated solution approached simple-structure conditions, with most main loadings in the 0.7 to 0.9 range and secondary loadings below 0.30. The only two exceptions detected were: (a) item 3 was found to be factorially complex, possibly because it informs of the different treatment options in a personalized way, and (b) residuals corresponding to items 8 and 9 were found to be correlated, both address treatment choice and application. Finally, the correlation between both factors was determined to be substantial ($r = 0.69$, $p < 0.001$).

**Confirmatory factor analysis**

Given the clear EFA results summarized above, a CFA solution was fitted to the data with the following specifications: factor 1 was defined by items 1 to 5; factor 2, by items 6 to 9; item 3 was allowed to load on both factors, and the residual corresponding to items 8 and 9 was set free. With these specifications, the fit of the proposed model in the entire sample was found to be quite acceptable. The estimates of this model in standardized metrics are presented in Figure 2.

**Scoring and reliability**

The factor analysis solution discussed above indicates that the SMD has a clear structure in two, closely correlated factors. Hence, these factors can be also viewed as components or facets of a more general dimension of perspectives regarding the decision-making processes. It follows then that two scoring strategies can be derived from this solution: first, to use scores on two sub-scales (i.e. information and treatment), and, second, to use total scale scores based on all items SMD. In the first case, reliability estimates based on factor scores were: 0.82 (information) and 0.88 (treatment). In the
second case, estimated reliability for total scores was 0.90. If raw scores were used instead, the corresponding reliability estimates (omega coefficients) were: 0.81 (information), 0.87 (treatment), and 0.88 (total). Overall, no substantial reliability gains appear to be attained by using factor scores and the simple raw scores achieve acceptable degrees of accuracy in all cases. Whether using 2 subscale scores is preferable to using a total score in clinical assessment is a matter for further research.

**Association with physicians’ satisfaction**

As shown in Table 3, the results revealed significant correlations between the total SMD-Q-Doc score and physician satisfaction with the information provided ($p<0.01$); between information sub-scale scores (factor 1) and satisfaction ($p<0.01$), and between treatment sub-scale scores (factor 2) and satisfaction ($p<0.01$). Insofar as physicians’ age and years of experience, the older the physician and more years of experience, the greater interest the physician tends to display in patient preferences ($p=0.026$ and $p=0.020$, respectively). Patient age negatively correlated with SDM-information ($p<0.01$), physicians appear to provide more information to young patients.

**Discussion**

Several instruments have been developed in recent years to evaluate the SDM process and doctor-patient encounters with specific aims [16] shedding more light on the complexity of this process. The objective of this study was to analyze the psychometric properties of the SDM-Q-Doc created by Scholl et al. [9] in a sample of medical oncologists who care for patients with non-metastatic resected-cancer. The Spanish version of the scale showed a clear and interpretable factor structure that was close enough to simple structure to be well fitted by a CFA solution. In this solution, all the items display high main loading values (meaning that they have good discriminating power) and the scores derived from the FA solution had acceptable reliability on all the schemata considered. The good reliability results are consistent with those obtained in the original German and Dutch versions, in which Cronbach’s alpha values based on the complete scale scores were between 0.88 and 0.87, respectively [9,17]. Although the two-factor solution was deemed the most appropriate, the substantial inter-factor correlation makes it compatible with a conceptualization of the two factors as facets of a more general dimension.

The physicians in general and the oncologists in particular are interested in participating in SDM with their patients [18, 19]. In our study, medical oncologists scored high on items related to providing patients with a good knowledge base about the advantages and disadvantages of treatment and in helping them to understand all the information (factor 1). The high score on the item “I helped my patient understand all the information”
indicates that the physicians in our sample are willing to give patients an active role in the decision-making process. However, they scored lower on items that involved patient participation in the final SDM (factor 2) “I asked my patient which treatment option he/she prefers”. In order to involve the patient in SDM, physicians first need to know whether their patients want to be more active participants in the decision-making process. Secondly, they must look at what role would be the most appropriate for the patient and, in many cases, the professionals are the ones who finally choose the treatment because the patient wants them to. There are numerous benefits to SDM in cancer treatment; for instance, patients feel more committed to the decision and are more satisfied with their treatment and with their physicians [20,21].

In the present study, the total SMD-Q-Doc score was unrelated to patients’ gender and age, but did correlate with physicians’ gender, age, and years of experience. Female oncologists tend to feel that they provide more information and that they are more interested in patients’ treatment preferences. With age and more years of experience, the physicians tend to engage their patients more in SDM. Similarly, in their review, Tarima et al. [22] found that physicians’ years of experience, communication style, and personal beliefs and values influence the SDM process. There is little information available about the factors that affect oncologists’ preferences to foster the use and support for SDM. In an interview conducted with 22 Australian oncologists, hematologists, and surgeons, physicians’ perceptions and values were seen to sway their support of SDM. Some physicians felt that not facilitating SDM was a sign of arrogance and that including patients in SDM reduces patients’ anxiety. Still others had their doubts as to including patients in the decision-making process because they considered that the patients might make the wrong decision [23].

The SDM-Q-Doc is the first psychometrically tested instrument to assess SDM from the physician’s perspective in a sample of cancer patients. Despite its strengths, this study does present certain limitations that must be taken into account in future research. First of all, although we have worked with a large sample, the participants in this study were patients with a localized tumor who had undergone surgery. In the future, it would advisable to expand the sample to include other tumor stages with the aim of confirming these results, as well as to compare different clinical-pathological and social variables. Secondly, the SDM-Q-Doc’s self-report subjective measures cannot accurately reflect patients’ experiences, expectations, and behavior, having limitations such as response bias (social desirability, inaccurate memory, etc.) and their difficulty in fully comprehending the SDM process [24]. Finally, in addition to this type of design, it would be fitting to explore the dynamic nature of SDM processes with other longitudinal studies that make it possible to study SDM in greater depth, examining its effects before and after a decision is made.
In conclusion, within the context of the patient with a non-metastatic resected-cancer, the “Shared Decision Making Questionnaire-physician version” has good psychometric properties, similar to those previously published [9,19]. It is a simple, short, reliable, and consistent measure of physicians’ perspectives of SDM. Likewise, in light of the results obtained, oncologists’ involvement in these types of decisions poses benefits for patients’ health and wellbeing, in line with the perceived satisfaction.

SDM is a process aimed at becoming acquainted with patients’ preferences and needs to empower them to take an active role in caring for their health in a manner that is consistent with their wishes. The SDM-Q-Doc can be a helpful tool in studies that examine physician’s perspective of SDM and as an indicator of quality and satisfaction in patients with cancer.

Compliance with ethical standards
Conflict of interest: None to declare. This is an academic study.

Funding source: The study was supported by the FSEOM-Onvida for Projects on Long Survivors and Quality of Life. SEOM (Spanish Society of Medical Oncology) 2015.

Ethical statement: The study has been performed in accordance with the ethical standards of the Declaration of Helsinki and its later amendments. This study is an observational trial without intervention.

Informed consent statement: Signed informed consent was obtained from all patients.
References


Figure 1. Participant flow chart

Invited to participate
562 patients
32 physicians

15 patients met exclusion criteria
14 patients did not meet inclusion criteria

Recruitment
533 patients
32 physicians

Excluded
13 patients with incomplete data

Data analysis
520 patients
32 physicians
Figure 2. Standardized solution for the SDM-Q-Doc confirmatory factor model.

Confirmatory factor analysis model fitting results: Root Mean Square Error of Approximation (RMSEA): 0.08, goodness-of-fit-index (GFI): 0.98, the root mean square of the standardized residuals (z-RMSR): 0.04, CFI: 0.99.
Table 1. Physicians’ and patients’ characteristics.

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<td>Male</td>
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<td>Specialized</td>
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<td><strong>Type of hospital</strong></td>
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<tr>
<td>Non-teaching</td>
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<td>46.9</td>
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<td>35.0 (7.4)</td>
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<td><strong>Number of years employed, mean (SD)</strong></td>
<td>11.9 (8.8)</td>
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<td>67.1</td>
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<tr>
<td><strong>Age, years, mean (SD)</strong></td>
<td>59.2 (12.2)</td>
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<td><strong>Married/partnered</strong></td>
<td>401</td>
<td>77</td>
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<td><strong>Primary educational level</strong></td>
<td>361</td>
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<td><strong>No working</strong></td>
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<td>64.6</td>
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<td><strong>Tumor side</strong></td>
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<td>Colon</td>
<td>210</td>
<td>40.4</td>
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<tr>
<td>Breast</td>
<td>183</td>
<td>35.2</td>
</tr>
<tr>
<td>Stomach</td>
<td>32</td>
<td>6.7</td>
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<tr>
<td>Others</td>
<td>95</td>
<td>23.7</td>
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<tr>
<td><strong>Time since diagnosis (days, mean; SD)</strong></td>
<td>67.8 (99)</td>
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*Abbreviation: N: number; SD: standard deviation; %: percentage.*
Table 2. Exploratory Factor Analysis results of Shared Decision-Making Questionnaire – Physician version (SMD-Q-Doc).

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<tr>
<th>Questions</th>
<th>M</th>
<th>SD</th>
<th>Factor I</th>
<th>Factor II</th>
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<tbody>
<tr>
<td>1  I made clear to my patient that a decision needs to be made</td>
<td>4.75</td>
<td>0.53</td>
<td>0.887</td>
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<tr>
<td>2  I wanted to know exactly from my patient how he/she wants to be involved in making the decision</td>
<td>4.65</td>
<td>0.59</td>
<td>0.532</td>
<td></td>
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<tr>
<td>3  I told my patient that there are different options for treating his/her medical condition</td>
<td>4.62</td>
<td>0.65</td>
<td>0.575</td>
<td>0.313</td>
</tr>
<tr>
<td>4  I precisely explained the advantages and disadvantages of the treatment options to my patient</td>
<td>4.57</td>
<td>0.68</td>
<td>0.607</td>
<td></td>
</tr>
<tr>
<td>5  I helped my patient understand all the information</td>
<td>4.80</td>
<td>0.46</td>
<td></td>
<td>0.812</td>
</tr>
<tr>
<td>6  I asked my patient which treatment option he/she prefers</td>
<td>4.24</td>
<td>0.93</td>
<td></td>
<td>0.733</td>
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<tr>
<td>7  My patient and I thoroughly weighed the different treatment options</td>
<td>4.28</td>
<td>0.83</td>
<td></td>
<td>0.806</td>
</tr>
<tr>
<td>8  My patient and I selected a treatment option together</td>
<td>4.31</td>
<td>0.81</td>
<td></td>
<td>0.934</td>
</tr>
<tr>
<td>9  My patient and I reached an agreement on how to proceed</td>
<td>4.53</td>
<td>0.73</td>
<td></td>
<td>0.657</td>
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Score range from 0 (strongly disagree) to 5 (strongly agree).
Table 3. Descriptive and Pearson correlation between SMD-Q-Doc and physician satisfaction, patient and physician characteristics.

<table>
<thead>
<tr>
<th>Variables</th>
<th>SMD-Q-Doc Total</th>
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<tbody>
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<td>SMD- Information</td>
<td>0.87**</td>
<td></td>
<td></td>
</tr>
<tr>
<td>SMD- Treatment</td>
<td>0.92**</td>
<td>0.62**</td>
<td></td>
</tr>
<tr>
<td>SDM- Satisfaction</td>
<td>0.21**</td>
<td>0.24**</td>
<td>0.15**</td>
</tr>
<tr>
<td>Physician age</td>
<td>0.10*</td>
<td>0.06</td>
<td>0.10*</td>
</tr>
<tr>
<td>Number of years employed</td>
<td>0.10*</td>
<td>0.06</td>
<td>0.10*</td>
</tr>
<tr>
<td>Patient age</td>
<td>-0.09*</td>
<td>-0.15**</td>
<td>-0.04</td>
</tr>
</tbody>
</table>

Abbreviation: SMD: Shared Decision Making; SMD-Q-Doc: shared decision-making questionnaire – physician version; *: p < 0.05, **: p < 0.01.