ELSEVIER

Blood 142 (2023) 5072–5073

The 65th ASH Annual Meeting Abstracts

POSTER ABSTRACTS

902.HEALTH SERVICES AND QUALITY IMPROVEMENT - LYMPHOID MALIGNANCIES

Improving Therapeutic Adherence in Oncohematological Patients with a Software Application: The Margherita Study

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Background: Therapeutic adherence plays a key role in treatment outcomes. Novel technologies have the potential to support patients (pts) throughout their treatment journey, thereby improving therapeutic adherence. Additionally, technology support can aid in the collection of patient-reported outcomes (PROs).
Aim of the study: To evaluate whether a software application specifically designed to support oncohematological pts could improve therapeutic adherence. A comparison with a matched historical cohort was also performed. This study supports the registration of RITA as a class IIA medical device.
Methods: We conducted a phase II monocentric prospective study, enrolling oncohematological pts affected by different diseases. Pts were monitored and supported in managing complications by using a specifically designed APP, called RITA (Remote Intelligence for Therapeutic Adherence) for 3 months. Besides, RITA allowed collection of ePROs and quality-of-life (QoL) data, through the EQ-5D-5L questionnaire, activity of daily life (ADL) and instrumental activity of daily life (IADL) scale data. RITA supported pts, by providing informations for managing reported complaints. Pts were enabled to report the following vital parameters: blood pressure, heart rate, oxygen saturation, respiratory rate, temperature, glycaemia, and weight. RITA also connected patient and doctor when necessary. The primary endpoint of the study was therapeutic adherence measured as at least the 80% of the relative dose intensity (defined as the ratio of delivered dose intensity to the prescribed referenced dose intensity, expressed as a percentage) during the study period.
Results: Sixty-two pts received support with RITA (APP group). Median age was 72 years (range 19-94), with 45 patients having a lymphoproliferative disease and 17 patients having a myeloproliferative disease. Ten pts were enrolled at treatment start, while 52 were still on treatment. Thirty-six (58%) pts used the APP more than 14 days, and the median number of accesses was 3.5 for patients $\leq$ 50 years, and 10 for patients $>$ 50 years. Predefined therapeutic adherence (>80%), was 82.8%, 81.5%, and 85.2% after 1, 2, and 3 months, respectively. When compared with the matched historical controls, the likelihood of being adherent seems to be higher at all time points in the APP group pts; after 3 months, the OR for therapeutic adherence in multivariate analysis of the APP group was 3.02 (95% CI, 1.04-8.76) respect to the historical control. In the APP group, 12 emergency room accesses by 10 patients were recorded, with the following causes: hearth failure (4), infection (4), atrial fibrillation (2), asthenia (1), and hyperbilirubinemia (1). Overall, 4626 access to the APP were registered, 2410 in the older half, and 2216 in the younger half of the population. A total of 1560 ePROs were recorded, with 1080 being grade 1, 370 grade 2, and 26 grade 3. The most frequent complaints were fatigue, reported 876 times, then itching (123 times), decrease in vision (107 times), insomnia (58 times), declivous edema (42 times), flu-like symptoms (43 times), cough (37 times), diarrhea (33 times), pain (33 times), anxiety (31 times), fever (36 times), tingling (23 times), pollakiuria (19 times), nervousness (17 times), and dysgeusia (17 times). The following clinical parameters were recorded: blood pressure (1652 times), heart rate (1538 times), oxygen saturation (1145 times), respiratory rate (227 times), temperature (1357 times), glycaemia (285 times), and weight (1439 times). The EQ-5D-5L questionnaire was completed by 50 (81%) pts at baseline, and 16 (26%) pts at 3 months. ADL and IADL

questionnaires were completed by 43 (69%) pts at baseline, and 14 (23%) pts at 3 months. No side effects related to the APP were recorded.

Conclusions: This is the first study demonstrating the efficacy of an APP in improving the therapeutic adherence in oncohematological patients. Furthermore, RITA allowed the collection of relevant ePROs, clinical parameters, and QoL data. Interestingly, several grade 1 and 2 ePROs were recorded, suggesting that RITA can improve the collection of low-grade adverse events respect to traditional methods. (Founded by Advice Pharma, NCT05260203).

Disclosures Carlo-Stella: *Janssen Oncology:* Honoraria, Membership on an entity's Board of Directors or advisory committees; *Takeda:* Honoraria; *Novartis:* Honoraria, Membership on an entity's Board of Directors or advisory committees; *Gilead:* Honoraria; *Incyte:* Honoraria; *Celgene/BMS:* Honoraria, Membership on an entity's Board of Directors or advisory committees; *AstraZeneca:* Honoraria; *Roche:* Honoraria, Membership on an entity's Board of Directors or advisory committees, Research Funding; *ADC Therapeutics:* Consultancy, Honoraria, Membership on an entity's Board of Directors or advisory committees, Research Funding; *Sanofi:* Consultancy, Membership on an entity's Board of Directors or advisory committees, Research Funding; *SOBI:* Honoraria, Membership on an entity's Board of Directors or advisory committees.

https://doi.org/10.1182/blood-2023-180245