

Patient-centredness is pivotal in a prospective dose reduction trial of tyrosine kinase inhibitors in patients with chronic myeloid leukaemia

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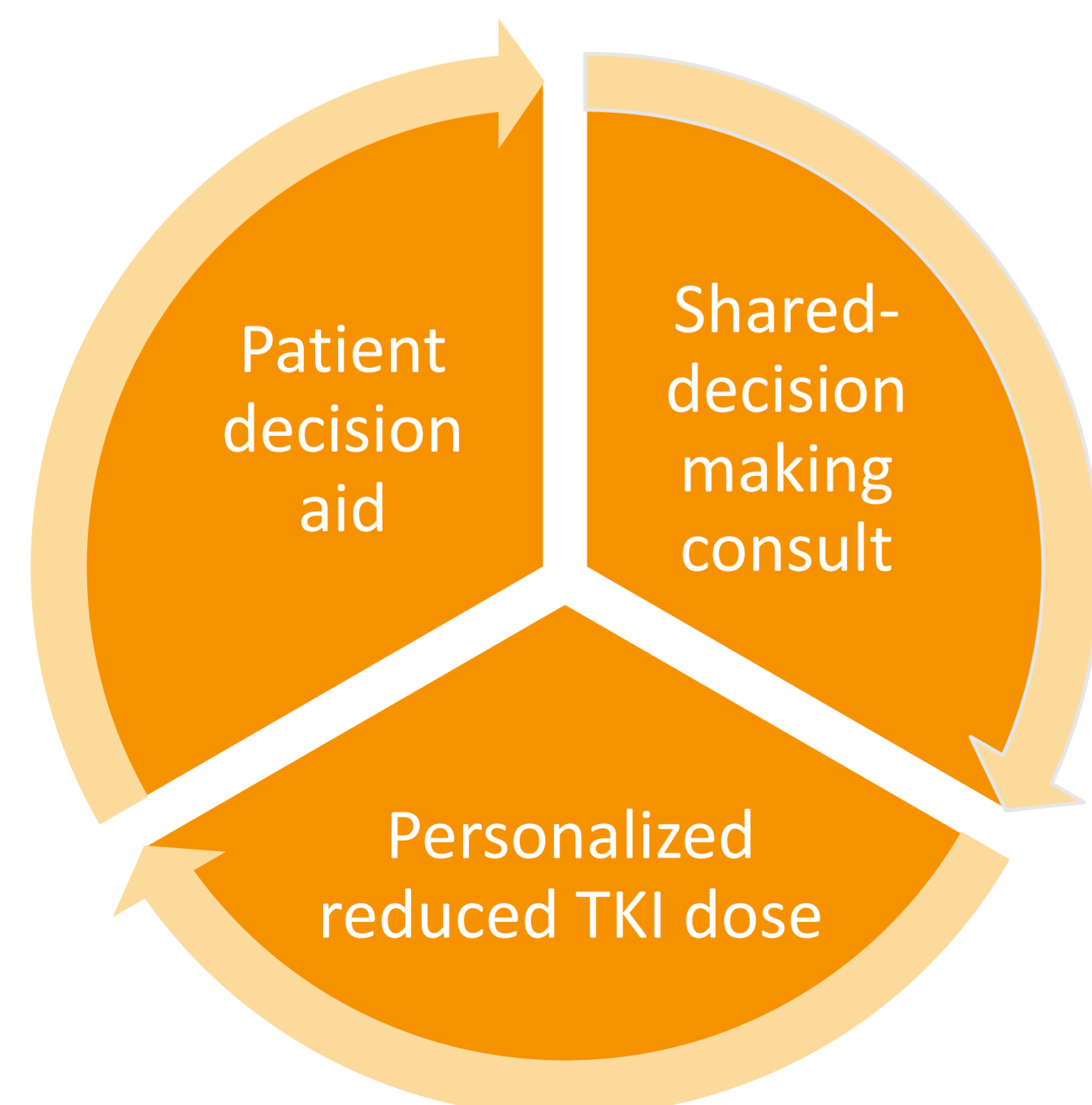
Introduction

Dose reduction of tyrosine kinase inhibitors (TKI) for patients with chronic myeloid leukaemia (CML) can reduce side effects and medication costs while maintaining therapeutic effectiveness.

OBJECTIVE

To develop and evaluate a **patient-guided dose reduction strategy**, consisting of a patient-decision aid to guide decision making and a shared decision-making consultation to discuss patient's willingness for dose reduction and to define a personalized dose.

Intervention components



Methods and key findings

1. INTERVENTION DEVELOPMENT

Methods: Complex intervention guided by Medical Research Council framework. Needs assesment with semi-structured interviews with 19 CML patients and 12 healthcare providers
Iterative design process with 18 patients and 16 healthcare providers
Results: Patients and healthcare providers supported dose reduction. Information about personal possibilities for dose reduction and potential risks was considered essential to make a well-informed decision.

2. PILOT TESTING

Methods: Testing of intervention components with 6 patients and 3 healthcare providers on acceptability and practical feasibility
Results: Intervention accepted by participants and feasible to use in practice

3. EVALUATION

Methods: Prospective, multicentre, single-arm trial with 147 CML patients with stable disease receiving the intervention
Primary outcome: proportion of patients with intervention failure, defined as patients who restart their initial dose due to (expected) loss of major molecular response at 12 months follow-up
Secondary outcomes: validated PROMs for side effects, quality of life, medication adherence and beliefs
Results: see Table

The trial evaluating of the patient-guided dose reduction strategy is ongoing. Access the study protocol here:



Conclusion

Patient-directed dose reduction using shared decision-making personalizes TKI treatment without loss of effectiveness

Table 1: Interim results of patients with 6 month follow-up after intervention

TRIAL INTERIM RESULTS	
Participants	65/94 male (69.1%); median age 59.5 years (range: 19-84)
Treatments	imatinib n=45 (47.9%) 2 ND generation TKI n=49 (52.1%)
Molecular response	MMR n=13 (13.8%) DMR n=71 (75.5%)
Dose reductions provided	17-50% of initial dose most patients (n=35, 37.2%) received 25% reduction
Treatment failure	n=3 (7.9%) intervention failure n=8 (20.5%) molecular increase n=5 (12.8%) deeper molecular response n=25 (64.1%) remained in baseline response status