



# PSYCHOSIS-RELATED ADVERSE EVENTS IN PEDIATRIC PATIENTS WITH ACUTE LYMPHOBLASTIC LEUKEMIA DURING DEXAMETHASONE-INCORPORATED TREATMENT IN JAPAN.

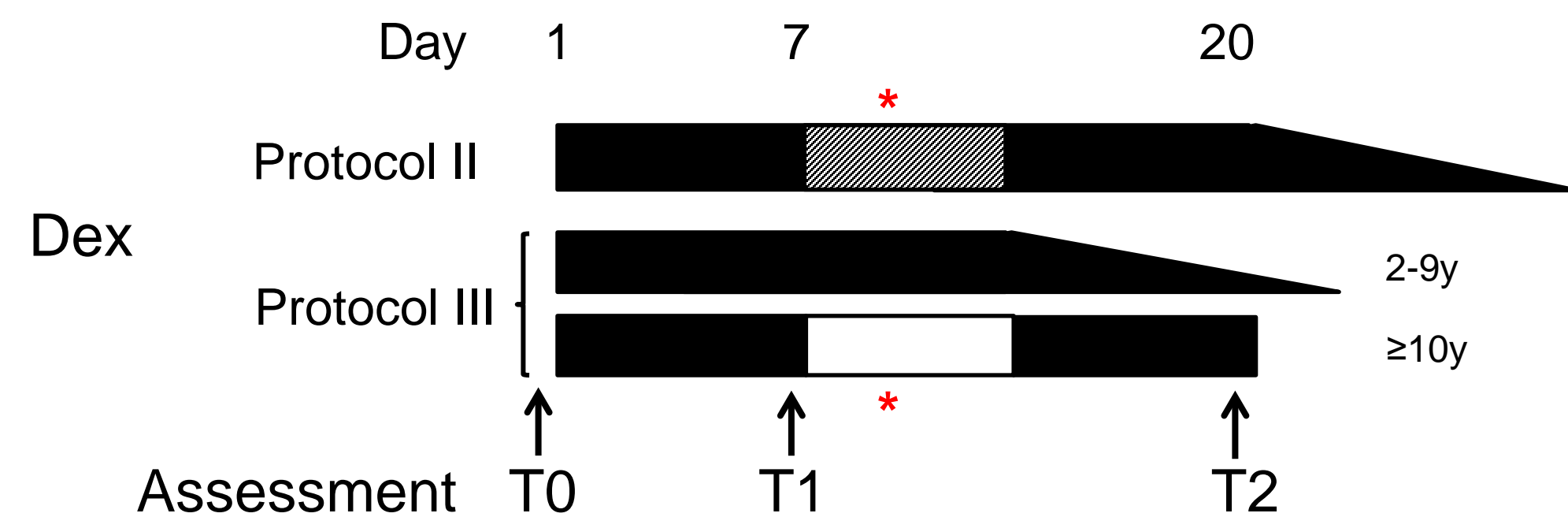
Shinya Osone<sup>1,2</sup>, Keitaro Fukushima<sup>2</sup>, Naoko Mori<sup>2</sup>, Takashi Ishihara<sup>2</sup>, Hirotohi Sakaguchi<sup>2</sup>, Souichi Suenobu<sup>2</sup>, Atsushi Sato<sup>2</sup>, Yasuhiro Okamoto<sup>2</sup>, Kyoko Tanaka<sup>3</sup>, Miho Maeda<sup>2</sup>, Kiyoko Kamibeppu<sup>2</sup>  
 1. Department of Pediatrics, Kyoto Prefectural University of Medicine, Kyoto, Japan; 2. Japan Children's Cancer Group (JCCG); 3. Department of Psychosocial Medicine, National Center for Child Health and Development, Tokyo, Japan

## Introduction

- Given the integration of dexamethasone (DEX) for the re-induction therapy of pediatric acute lymphoblastic leukemia (ALL) since 2011, psychiatric adverse events (AEs) have surfaced in Japan.
- Previous Japanese study using physician-reported outcome reported that 3/62 (1.7%) ALL cases with DEX were affected by psychiatric AEs<sup>1</sup>. However, the precise incidence by patient- or caregiver-reported outcome remains undisclosed.
- This investigation seeks to elucidate the frequency of depression during re-induction therapy with DEX.

## Methods

- This multicenter prospective observational study enrolled children with ALL in first complete remission aged 2 to 18 from December 2020 to August 2022.
- Patients aged 6 years and older underwent assessment using the Birlson Depression Self-Rating Scale for Children (DSRS-C) just before (T0), as well as 1 (T1) and 3 (T2) weeks after commencing the Berlin-Frankfurt-Münster-backbone re-induction therapy containing DEX.
- Family caregivers concurrently reported the Strengths and Difficulties Questionnaire (SDQ) at corresponding time points.
- Exclusion criteria: Ph+ALL, The cases using psychotropic, antianxiety or sleep-inducing drugs at T0



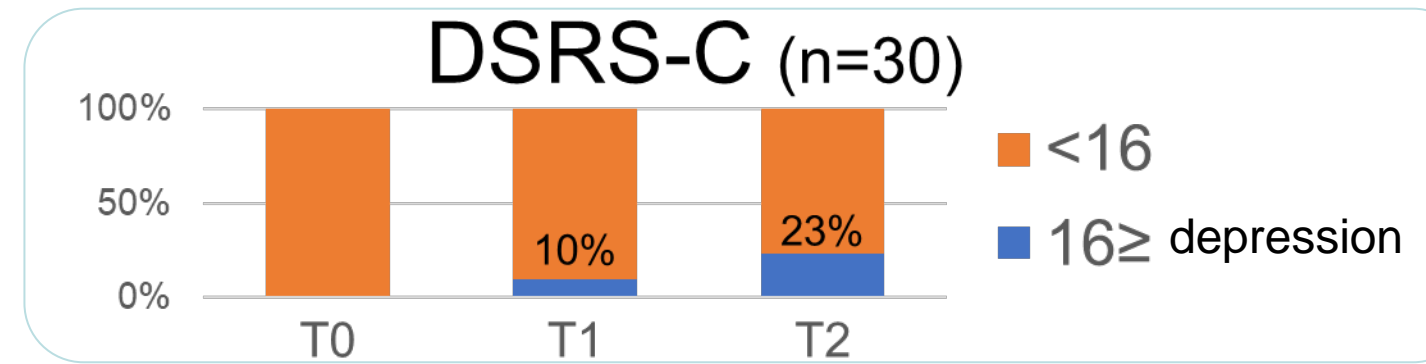
\* DEX was intermitted from day 8 to day 14 for the patients aged 10 and older to mitigate the risk of osteonecrosis.

- Depression was defined as a DSRS-C score of 16 points or higher. Ratios of patients with depression at T1/T2 but without at T0 were calculated.
- Ratios of patients with high need for support, defined by SDQ total difficulties scores (TDSs) and its subscales at T1/T2 but without at T0, were also computed.
- Simultaneously, information concerning physical AEs potentially influencing the psychological well-being of the patients (pain, nausea & vomiting, diarrhea, infection, pancreatitis, stomatitis, allergic reaction, dyspnea) was collected.
- This study was approved by the institutional review board of the Kyoto Prefectural University of Medicine (ERB-C-1894-2). Informed consent was obtained from the caregivers and patients if possible.

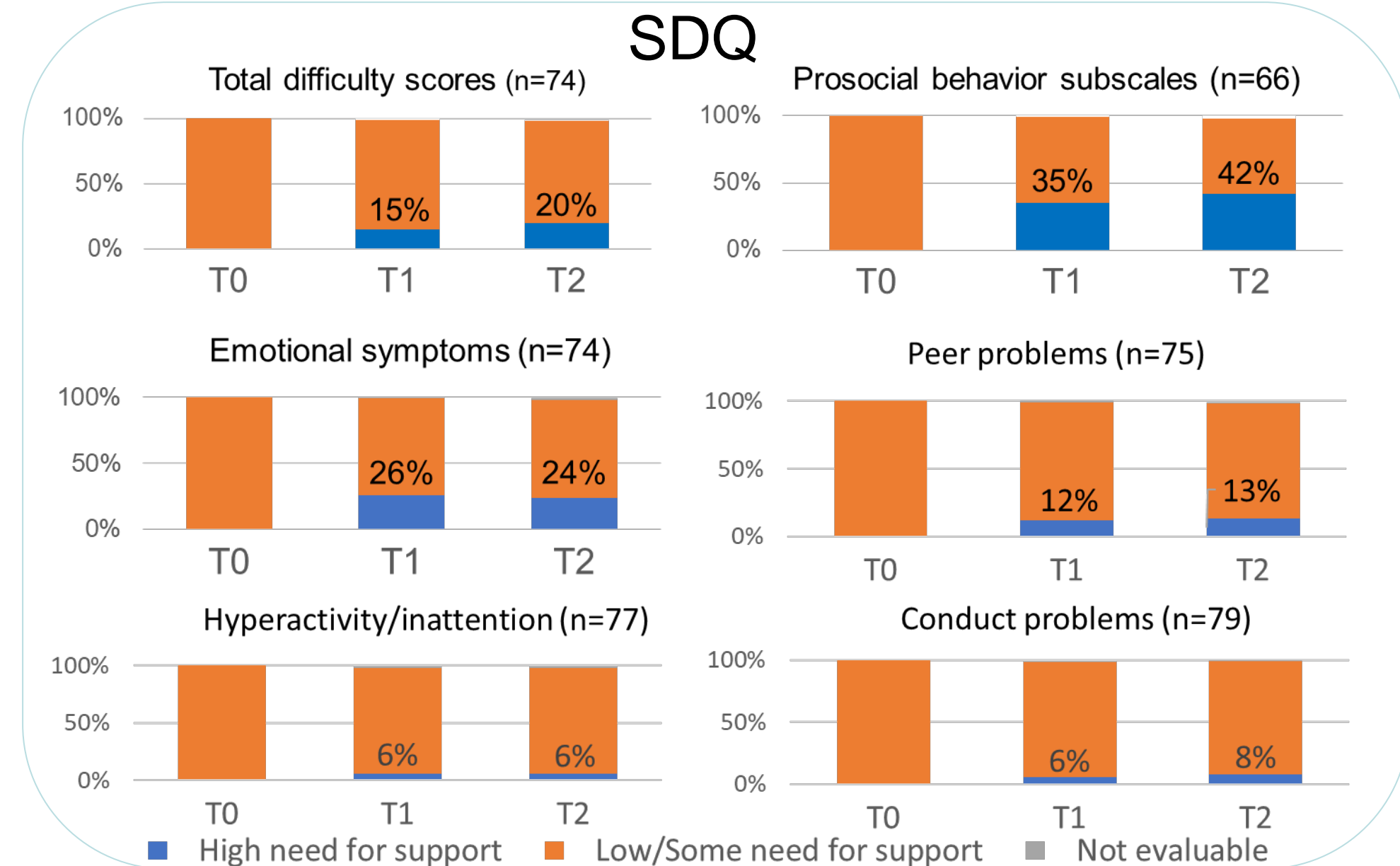
## Results

Patient Characteristics		Number (%)
Age	2-5*	47 (57)
	6-18	36 (43)
Sex	Male	50 (60)
	Female	33 (40)
ALL phenotype	B	74 (89)
	T	9 (11)
Therapy	Protocol II	36 (43)
	Protocol III	47 (57)
Comorbidity	Yes	6 (7)
	No	77 (93)
CNS involvement at the onset of ALL	Yes	2 (2)
	No	81 (98)
CNS complications due to prior ALL therapy	Yes	5 (6)
	No	78 (94)
Family history of psychiatric disorders	Yes	2 (2)
	No	81 (98)

\*: SDQ only



These adverse alterations were observed irrespective of physical AEs.



## Conclusions

- DEX-containing re-induction therapy elicited psychiatric AEs in a substantial proportion of children with ALL in Japan.
- The development of strategies to ameliorate these distressing AEs is imperative.

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## References

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The authors have no conflicts of interest to disclose.